

EXHIBIT A-10

[*Available at* <https://www2.hse.ie/file-library/cervical-screening/interval-cancer-report-cervicalcheck.pdf> (last checked on November 8, 2021)]

[Although the entire report is attached hereto as Exhibit A-9, relevant excerpts are highlighted for the Court's convenience.]

[Judicial notice may be taken of this report because it is an official publication of a government agency. *See Hawk v. Chao*, 418 F.3d 453, 457 (5th Cir. 2005) (judicial notice of agency materials on website).]

[This report is attached to respond to and rebut arguments made by Plaintiff in its response brief. *See Perez v. Genesco*, No. 09-cv-22, 2010 WL 11602142, at *2 (W.D. Tex. Jan. 8, 2010) (accepting evidence on reply because it served “to rebut arguments offered [in] Response”).]



Expert Reference Group

Interval Cancer Report CervicalCheck

October 2020



An tSeirbhís Náisiúnta Scagthástála
National Screening Service


CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

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Foreword

International data demonstrates that cervical cancer screening saves lives, nevertheless, the inherent limitations of cervical cytology means that screening will fail to prevent cancer in up to a third of diagnosed cases. In Ireland, CervicalCheck, the National Screening Programme which began in 2008, has performed as well, and in some circumstances, better than published data from other countries. Quality assurance, quality improvement and professional education are essential to maintain optimal performance. As one element of a broad quality assurance programme, CervicalCheck conducted an audit of cytology in all women who developed invasive cervical cancer in the first eight years of the programme. Issues arose in 2018 in relation to inconsistent disclosure of the audit results to patients. The subsequent Scoping Inquiry into the CervicalCheck Programme, conducted by Dr. Gabriel Scally in 2018, identified areas for improvement in screening and made a broad range of recommendations which included emphasis on quality assurance, the importance of audit, open disclosure with patients and improved linkage with the National Cancer Registry.

The Expert Reference Group on Clinical Audit of Interval Cancers in the CervicalCheck and BowelScreen Screened Population was established in 2019 to address one element of quality assurance: how best to conduct audit by clinical experts of interval cancers arising between screening visits. It has been my privilege to chair the Expert Reference Group, which comprised representatives from professional disciplines, international expertise and patient and public members. I would like to thank all participants for the time and energy they devoted to this complex project, especially the patients and public members and the international experts who either attended or provided detailed input into our deliberations.

We focused on learning from international practice, through reviewing the published literature, conducting a survey of the approach to audit in well-established programmes and discussions with International Screening experts. In Ireland, we considered patient and public expectations, HSE policies, the National Screening Programme's data, Irish legislation and lessons learned from the Scally report and the Royal College of Obstetricians and Gynaecologists (UK) Expert Panel Review of Cervical Screening in cases of cervical cancer in Ireland between 2008-2018. We noted that CervicalCheck was performing within international parameters. We learned that there is no international consensus or standards on clinical audit of cytology, some countries do not audit cytology, others audit but do not disclose, some jurisdictions have legislative protection from disclosure of audit findings, a few countries audit and advise treating clinicians of the result, and one advises patients directly. Where countries carried out audit of cytology, the focus was on audit for all cancer patients, not just those with interval cancers. Where cytology audit has been published internationally, cytology was discordant in 30-55% of cancers.

Our final recommendations have three themes:

1. Individual case reviews may be requested by a patient, including cytology and programme performance, based on signed consent, to ensure patients have access to their own information if desired. This will be available to any patient who develops an invasive cancer, not just an interval cancer.
2. Retrospective programmatic review of cytology in patients with invasive cancers will be conducted which will be anonymised and blinded or under an agreed legislative framework, to ensure that the key deliverables of quality assurance and professional education are sustained.
3. CervicalCheck will develop a new Programmatic key performance indicator, the annual interval cancer rate.

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We recognise that our recommendations will offer more comprehensive audit processes than are typically conducted in other cervical screening programmes. In the absence of established international standards, we have proposed an approach which is an improvement on current practice and which should help build patient and public confidence and trust as well as providing the education and training of professional staff.

Serious concern has arisen recently that the growth in number of legal claims against CervicalCheck will affect its viability. The effect of this is two-fold: recruitment and retention of professional staff may worsen or the costs of litigation may greatly exceed the resources available to sustain the Programme, putting CervicalCheck at risk of collapse.

The public and patients will learn from reading our report that when cytology is audited knowing that a patient has cancer, reviewers expect to find a high level of discordance. In this regard CervicalCheck's performance is consistent with international data.

Cervical cancer screening not only saves lives in Ireland, it reduces the risk of permanent consequences of treating an invasive cancer, such as infertility. Sustaining a highly performing programme requires a balance of all elements including patient trust, staff recruitment and affordability. These issues need to be addressed honestly and openly if we are to sustain this vital public health programme.

Professor Susan O'Reilly

MB, BCh, BAO, FRCPC, FRCPI.

Glossary of terms, definitions and abbreviations

Term	Definition
ASCUS	Atypical Squamous Cells of Undetermined Significance
ASMR	Age-Standardised Mortality Rate
BCCA	British Columbia Cancer Agency
BC	British Columbia
CIN	Cervical Intraepithelial Neoplasia
CSPL	Cervical Screening Provider Lead
Clinical Audit	As defined by the Health Service Executive (HSE), "Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements". (1) It should be noted that the term is also frequently used for generic quality review processes.
False Positive	Samples where the test is reported as abnormal but the disease is not present.
False Negative	Samples where the test is originally reported as negative but on review abnormal cells are found.
GDPR	General Data Protection Regulation
GP	General Practitioner
HSE	Health Service Executive
HSIL	High Grade Squamous Intraepithelial Lesion
HPV	Human papillomavirus, which can cause cervical and other cancers
IARC	International Agency for Research on Cancer
Interval cancer	A primary cervical cancer diagnosed in a woman after a negative screening test, but before the next invitation to screening is due, or within a period equal to a screening interval for a woman who has reached the upper age limit to attend screening.
KPI	A key performance indicator (KPI) within CervicalCheck is a predefined parameter by which the performance of a cervical screening programme is assessed.
LSIL	Low-Grade Squamous Intraepithelial Lesion
MoU	Memorandum of Understanding
NCRI	National Cancer Registry Ireland
NHS	National Health Service (Britain)
PEU	Programme Evaluation Unit
PICO	Populations, Interventions, Comparators, Outcomes
PHE	Public Health England
PHW	Public Health Wales
RCOG	Royal College of Obstetricians and Gynaecologists (UK)
Smear test	Examination by professionally trained laboratory staff (cytologists) of a sample of cells taken from the woman's cervix by a health professional. This is currently referred to as a cervical cytology test.
SOP	Standard Operating Procedure
SQAS	Screening Quality Assurance Service
TOR	Terms of Reference
UK	United Kingdom

Section One: Executive Summary

Cervical cancer in Ireland

- Cervical cancer is the eighth most common cancer in Ireland. Each year, more than 260 women are diagnosed with cervical cancer and almost 90 women die of cervical cancer. Almost half of women diagnosed with cervical cancer are aged 45 years or under.
- Cervical cancer is a worldwide problem principally caused by persistent, high-risk human papillomavirus (HPV) infections which cause changes to the cervical cells. If the virus persists in a woman's cervix (neck of uterus), chronic inflammatory changes in the cells lining the cervix may lead to precancerous changes, known as cervical intraepithelial neoplasia (CIN), and may, with time (often years), go on to develop into cancer. Fortunately, early changes in these cells can be detected through screening and lead to investigation and treatment in order to prevent more serious disease.

Screening for cervical cancer

- The first cervical screening (smear test) was developed in the 1940s and has been available as a screening test since the 1960s.⁽²⁾ Many international cervical cancer screening programmes employ repetitive cytology testing offered to the entire population of healthy women in a specific age group (previously 25–60 years in Ireland). HPV testing is now increasingly used for primary cervical cancer screening in conjunction with smear (cytology) tests for HPV-positive cases.⁽³⁾ Both the smear test and the HPV test are simple, safe, affordable tests which are easy to administer and acceptable to women.
- The smear (cytology) test is not designed to diagnose cervical cancer. The primary purpose of cervical cancer screening is detection of precancerous changes and prevention of cancers, but it also permits the early detection of a cancer when it is most likely to be treatable and curable. The goal of a cervical screening programme is to reduce the incidence of and mortality from, cervical cancer in an overall population of healthy women at risk.

Interval cancers

- An interval cervical cancer is defined as “A primary cervical cancer diagnosed in a woman after a negative screening test, but before the next invitation to screening is due, or within a period equal to a screening interval for a woman who has reached the upper age limit to attend screening”.⁽⁴⁾
- No screening test is 100% accurate. Some results can be false negatives (i.e. the test result is negative, although the disease is actually present) and a small number of results can be false positives (i.e. the screening test says the result is positive, but no clinically significant disease is found on further testing). False negatives cause a delay in diagnosing precancerous changes, which could then progress to cervical cancer. False positive results lead to unnecessary investigation, potentially harmful consequences, and anxiety.
- Typically, if 1,000 women are screened, about 20 women will have abnormal cervical cells; about 15 of these women will have these cells found through smear test screening, and about 5 women will not have these cells found through smear test screening and may develop cervical cancer.
- HPV testing is a more sensitive test than the smear test. For every 1,000 women screened, 20 will have precancerous changes; HPV testing will correctly identify 18 of these women, whereas cytology smear testing will identify about 15 women, as stated above. CervicalCheck introduced primary HPV testing in 2020.

CervicalCheck – The National Cervical Screening Programme

- CervicalCheck – The National Cervical Screening Programme was established in Ireland in 2008. Between 2008 and 2018, more than 3 million cytology tests were carried out in 1.2 million women aged 25–60 years. Tests were performed in accredited laboratories and detected more than 64,000 high-risk precancerous changes and 1,500 cancers. These numbers highlight the benefits of CervicalCheck. At the end of the ninth screening year (31 August 2017), the screening programme’s 5 year coverage reached 80%.⁽⁵⁾

Quality assurance in CervicalCheck

- As part of quality assurance, CervicalCheck monitors and publishes a range of key performance indicators (KPIs) aligned with the *European guidelines for quality assurance in cervical cancer screening*.⁽⁶⁾ One element of quality assurance and professional education relates to the audit of cytology following a diagnosis of an invasive cervical cancer. Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.⁽¹⁾

- In Ireland, an audit of cytology in all women known to be diagnosed with invasive cervical cancers in the first 8 years of the CervicalCheck programme was undertaken. In total, 1,482 cases were reviewed, of which 1,296 had participated in CervicalCheck. In 221 cases (15%), the cytology review indicated discordance with a previous smear test (of note, these 221 cases comprised approximately 1 in 5,400 women who participated in screening). In 2018, publicity surrounding this audit resulted in the Minister for Health commissioning a Scoping Inquiry into the CervicalCheck Screening Programme, which was conducted by Dr Gabriel Scally and published in September 2018.⁽⁷⁾ The recommendations of Dr Scally's report are now being implemented.

Open disclosure

- The Health Service Executive (HSE) Open Disclosure Policy has been available since 2013. The Expert Reference Group endorses its use in circumstances where patient safety incidents arise (clinical incidents or harms) which are “unintended or unanticipated”.⁽⁸⁾ Retrospective audit of cytology is expected to show discordance in between 30% and 55% of slides from women diagnosed with invasive cervical cancer, based on international evidence. Therefore, discordant cytology alone does not constitute an “unintended or unanticipated” incident.
- The HSE National Quality Improvement team made an interim revision to the HSE Open Disclosure Policy on 12 June 2019, which replaced the HSE Open Disclosure Policy dated 8 October 2013.⁽⁹⁾ The interim policy states that it “will be subject to further review following: (i) the development and publication of operational guidance for clinical audit of interval cancers in screening services by the Expert Working Group on the Clinical Audit of Interval Cancer in the CervicalCheck Screened Population. This guidance will set out the principles and processes for how audit and individual case review should be undertaken following a diagnosis of interval cancer in the screened population and (ii) the commencement of provisions for mandatory open disclosure in the forthcoming Patient Safety Bill”.⁽⁹⁾

Expert Reference Group

- In 2019, the HSE established two Expert Reference Groups: one for BreastCheck and one for both CervicalCheck and BowelScreen. These groups were asked to “define the future audit processes and review guidance for interval cancers in the National Screening Service based on international evidence and best practice” (Appendix 1).
- The Expert Reference Group has recognised the rationale to report and monitor all interval and screen-detected cancers. The recommendations in this report focus on the following requirements:
 - 1) The obligation to patients to provide access to all of the information related to their care, including a review of their screening history and cytology communicated in a supportive and open way, once a patient wishes to have this information and provides consent.
 - 2) The requirement to conduct educational exercises as a key element of both the quality assurance of the programme, and of professional education and development in a manner that supports recruitment, retention and knowledge development in professional staff.

- 3) The necessity to develop a new KPI for the programme– the annual rate of interval cancer – and compare it with other international programmes.
- 4) The requirement for the programme to be affordable within the challenging environment of increasing demand for all health services. Cancer screening must be sustainable in order to achieve the benefits of reducing the incidence and mortality of cervical cancer in the screened population.

International practice

- Over the course of its work, the Expert Reference Group considered oral presentations and written submissions from a range of international experts. A review of peer-reviewed literature was completed and an international survey of population-based cervical cancer screening programmes was undertaken. The survey questionnaire and its results are detailed in Appendix 2. The summary findings of the survey are as follows:
 - The management of invasive interval cancers varies between international cervical screening programmes. Some international programmes do not examine interval cancers at any level.
 - Of the 17 countries/regions that completed the survey, 11 have an audit process in place for interval cancers; the remaining 6 countries/regions do not have an audit process for interval cancers. The majority of survey respondents have introduced HPV testing, with only three responding programmes relying exclusively on smear tests as of 2019. Although investigation of invasive interval cancer has heretofore focused on cytology, this practice is not universal.
 - The majority of international programmes do not disclose interval cancer audit results to their patients, as audits are regarded as educational exercises to improve service quality and staff performance. Some of these regions have legislative protection from disclosure in order to foster optimal staff participation in quality improvement.
 - A minority of the international programmes surveyed (three) have adopted a different approach to audit and disclosure. In England, Hospital Trusts are expected to directly inform patients of clinical audit findings and offer a meeting. The other two jurisdictions, Wales and Norway, notify the treating clinicians of the outcome of an audit and recommend that patients be offered a meeting.
 - Only three of the programmes surveyed calculated the interval cancer rate; thus, an international benchmark is not yet available.
- Similarly, the literature review has shown that there is no international consensus on what constitutes best practice for audit and disclosure of audit results of interval cancers in cervical screening programmes.
- Publications of the results of the National Health Service (NHS) Cervical Screening Programme's audits of invasive cervical cancers found discordances in both histology and cytology in previously screened women with confirmed diagnoses of cervical cancer.
- Public Health England (PHE) published its most recent quality assurance audit in October 2019.⁽¹⁰⁾ It reported on the 2013–2016 period and demonstrated, in an unblinded audit of cytology, that the previously negative findings in patients aged 25–49 who had interval cancers were upgraded in 42% of cases. These data are worth emphasising, as they clearly illustrate that since the cytology smear test is prone to significant observer variability, it cannot be considered a diagnostic test, nor can it provide absolute certainty that it rules out precancerous changes.

- Two United Kingdom (UK) screening programmes (in England and Wales) provide operational guidance on disclosure of audit results. Other international programmes have not published such guidance. Our review identified one 2015 study, which preceded Duty of Candour legislation but followed the introduction of open disclosure in England. The study found that despite National Cervical Screening Programme guidelines, only 53% of all responding clinicians offer review meetings to patients and those that did offer meetings did not offer them to all patients.⁽¹¹⁾ For the 47% of respondents who did not offer review meetings, the reasons cited were: lack of awareness of guidelines; time constraints; fear of causing distress; and, rarely, fear of litigation. This was consistent with a 2012 study⁽¹²⁾ that found low rates of disclosure.
- The difficulty in conducting audits of cervical cytology, or any retrospective review process, is that such audits are subject to hindsight bias. This was highlighted in the Scoping Inquiry into the CervicalCheck Screening Programme.

Recommendations

Section Five of this report provides an explanation to each of the recommendations and should be read in conjunction with this summary.

Recommendation 1: Women should continue to be provided with all the information they require in order to help them make an informed choice to consent to participate in the CervicalCheck programme. Current informational materials should be revised in order to reinforce the information on the benefits and limitations of screening. These materials should continue to include explicit information on the occurrence of interval cancers. They should also include information on how women can request a review of their case, if desired. Expanded content on data-sharing arrangements between CervicalCheck and the National Cancer Registry Ireland (NCRI) should be included. The Privacy Notice provided to patients in relation to their participation in the CervicalCheck Programme may need to be updated to explain what personal data the HSE will share with the National Cancer Registry Ireland (NCRI) and any other third parties, including but not limited to the purpose(s) of processing, the legal basis for processing, etc., to ensure compliance with data protection law.

Recommendation 2: CervicalCheck should establish a process to conduct patient-requested reviews of all invasive cancers (both interval and screen-detected cancers) and establish a standard operating procedure (SOP) for this purpose. Patient-requested reviews should only be undertaken following receipt of written consent from the patient. These reviews should be available to all women diagnosed with invasive cancers, including historic cases of women who did not participate in any other National Screening Service or Royal College of Obstetricians and Gynaecologists cytology review processes. Based on international experience, CervicalCheck should advise that a patient-requested review may take more than 12 months to complete.

Recommendation 3: The findings of all patient-requested reviews should be fully disclosed, and arrangements for this will be included in the CervicalCheck SOP. It is further recommended that the responsibility for disclosure of the review outcome rests with the treating clinician, generally the colposcopist or oncologist. This disclosure will be conducted in collaboration with the CervicalCheck programme and the woman's general practitioner (GP). CervicalCheck must notify the disclosing clinician of the outcome of the review, and in turn, the disclosing clinician must confirm with CervicalCheck that disclosure has taken place. Discordance in cytology review is not unexpected or unanticipated. This would not meet the definition of a patient safety incident. If a serious adverse event is identified, HSE policies must be followed.

Recommendation 4: The Expert Reference Group recognises the educational value of programmatic review of cytology of all invasive cancers including interval cancers. The Expert Reference Group therefore recommends that Clinical Audits be conducted only where either (1) such Clinical Audits are both blinded and anonymised; or (2) legislation protecting the confidentiality of Clinical Audits is passed by the Oireachtas. If such Clinical Audits are conducted, CervicalCheck will include the outcomes of such Clinical Audits in an annual report. The results of the Clinical Audits will be anonymised and/or confidential under future legislation, and therefore results of the Clinical Audits cannot and will not be disclosed in respect of individual cases reviewed.

Recommendation 5: The CervicalCheck programme should develop a new KPI, the interval cancer rate. The programme should liaise with other international screening programmes and the International Agency for Research on Cancer (IARC), specifically with regard to:

- Definition of interval cancers
- Methodology to calculate the interval cancer rate, and
- Benchmarking for participating programmes.

Recommendation 6: Implementation of the recommendations of the Scally Report should ensure that communication with NCRI is strengthened to enable a more timely validation of invasive cervical cancers. This includes consideration of the development of a population screening registry or equivalent in collaboration with the NCRI. Implementation of the individual health identifier would facilitate this process.

Recommendation 7: The HSE should continue to build and promote understanding, confidence and trust in CervicalCheck and other screening programmes through public information, engagement and education for participants, clinicians, and the wider society. Women should be made aware that they may, separately from any review process, request access to their screening records at any time.

Recommendation 8: The Expert Reference Group recommends that the necessary resources should be provided to CervicalCheck in order to implement these recommendations. An implementation team should be established in order to ensure continued implementation of disclosure according to the outlined recommendations. Processes should be continually monitored in the context of updates to the Patient Safety Bill 2018, the General Data Protection Regulation (GDPR), tort reform and emerging international practice.

Implementation of recommendations

The Expert Reference Group recognises that the recommendations in this report present significant planning and operational challenges for the CervicalCheck Programme. An Implementation Planning Committee is being established to develop the methodologies and standard operating procedures for these recommendations. Please refer to Section Five of this report for implementation details.

The challenges to successful implementation must be understood:

- The CervicalCheck programme has commenced primary HPV testing in 2020. Notwithstanding the priority afforded to the project, the logistical challenges posed by the roll-out of this methodology are significant; particularly in the context of the Covid-19 pandemic as screening programmes were paused following the lockdown and are now gradually reopening.
- In 2020, concerns have arisen in relation to ongoing growth in legal cases against CervicalCheck. The RCOG review concluded that the findings of their cytology review were in line with the patterns of discordance reported in audits of English cytology; overall, CervicalCheck was performing well and women can have confidence in the programme. Nevertheless, more litigation has arisen subsequent to this review. Furthermore, the Supreme Court ruling that a cytologist must have “absolute confidence” when reporting that a slide is normal has inadvertently created a misunderstanding that cytology reports must be 100% accurate, this is clearly unachievable.
- The CervicalCheck programme must be supported to continue to provide quality-assured, freely accessible public screening to current and future participants in order to reduce incidence and mortality from cancer. The balance between respect for the patients’ need to know their information in an open and supportive health care environment versus the duty to future participants and staff to maintain a viable programme has weighed heavily on our approach to implementation.

Patient-Requested Reviews: The HSE and the National Screening Service must engage with and inform the public, patients, politicians and media of the benefits and limitations of screening programmes. It is vital that screening participants appreciate that tests will substantially reduce their risk of developing cancer, but cannot prevent or diagnose all cancers and that interval cancers will arise in any population screening programme. A comprehensive communications plan must be developed and implemented prior to the roll out of Patient-Requested Reviews. The Expert Reference Group recognised that the conduct of Patient-Requested Reviews could influence legal claims which may potentially compromise retention of professional staff and costs of providing the Programme. The HSE, Department of Health and Government must consider putting safeguards in place to ensure sustainability of screening. A legal framework for screening needs to be explored.

Programmatic Audit of Cytology: The introduction of primary HPV screening this year will reduce cytology volume by 85% as cytology will only be carried out for women testing positive for HPV. Programmatic audit should be introduced prospectively for cytology arising in the primary HPV screened population. The Quality Assurance and professional education will be aligned with the new screening methodology. The Implementation Planning Committee will develop the Standard Operating Procedures for an anonymised and blinded review process. The audit processes will commence once resources (staff and funds) are available and the screening programme has resumed full operation.

Development of an Annual Interval Cancer Rate: This new Key Performance Indicator for CervicalCheck will be an additional programmatic audit measure, similar to BreastCheck. The parameters defining an annual Interval Cancer Rate must be agreed with other international screening programmes (and IARC). A standard rate (or range) must be developed. Data capture from the National Cancer Registry of Ireland must be developed and implemented and be compliant with data protection regulations. A Memorandum of Understanding with the NCRI has already been agreed. The Implementation Planning Committee can commence this project immediately, building on the current links between the National Cancer Registry of Ireland and NSS.

Conclusion

The Expert Reference Group brought together Irish professionals, patients, public representatives and international experts in order to evaluate international practices in cervical screening. Clinical audit is one important element of CervicalCheck's quality assurance programme. Investing in the recommendations of this report will address the needs of patients for full review and disclosure of their clinical management. Professional staff and programme participants will benefit from the focus on quality assurance and education. The development of a new KPI for the Programme, the interval cancer rate, will improve international benchmarking of the Programme's performance.

Section Two: Background

International burden of cervical cancer

In 2019, the International Agency for Research on Cancer (IARC) reported that the 2018 global cancer burden was 18.1 million new cases and 9.6 million cancer-related deaths.⁽¹³⁾ With regard to cervical cancer specifically, it is estimated that 570,000 diagnoses are made globally each year, with a reportedly higher incidence in developing nations.

Data from countries/regions with long-established screening programmes – for instance, Nordic countries and Western Canada, which have had programmes in place for more than 50 years – have demonstrated a 50–70% reduction in cervical cancer mortality. Long-term decreases in incidence rates for squamous cell carcinoma in particular correlate to organised screening programmes.⁽¹⁴⁾ In Canada, for example, the age-adjusted incidence of squamous cell carcinoma of the cervix declined from 11.1 per 100,000 women to 5.3 per 100,000 women between 1970 and 1996.⁽¹⁵⁾

Cervical cancer burden in Ireland

The National Cancer Registry Ireland's (NCRI's) May 2018 report shows that on average, there were 264 new cases of invasive cervical cancer each year between 2015 and 2017, and 88 deaths each year between 2012 and 2014.⁽¹⁶⁾ Figure 1 shows that there was a significant increase in the incidence of invasive cervical cancers in the period from 1994 to 2010, which was associated with opportunistic testing and the introduction of a pilot screening programme. This was followed by a significant (5.3% per year) reduction from 2010 to 2016, which is attributable to the implementation of population-based screening. This provides evidence to suggest that CervicalCheck, initiated in late 2008, is already reducing the incidence of cervical cancer in Ireland.⁽¹⁷⁾ The age-standardised mortality rate for cervical cancer (Figure 2) shows a trend to reduce mortality. It is important to note that it will take more years of population based cervical cancer screening to achieve the expected benefits in mortality reduction.

The latest data from the NCRI show that there was a significant reduction (approximately 1% per year) in the age-standardised mortality rate (ASMR) of cervical cancer in the period from 1994 to 2016.

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Figure 1. Trend in age-standardised incidence rate (ASIR) for invasive cervical cancer, 1994–2016

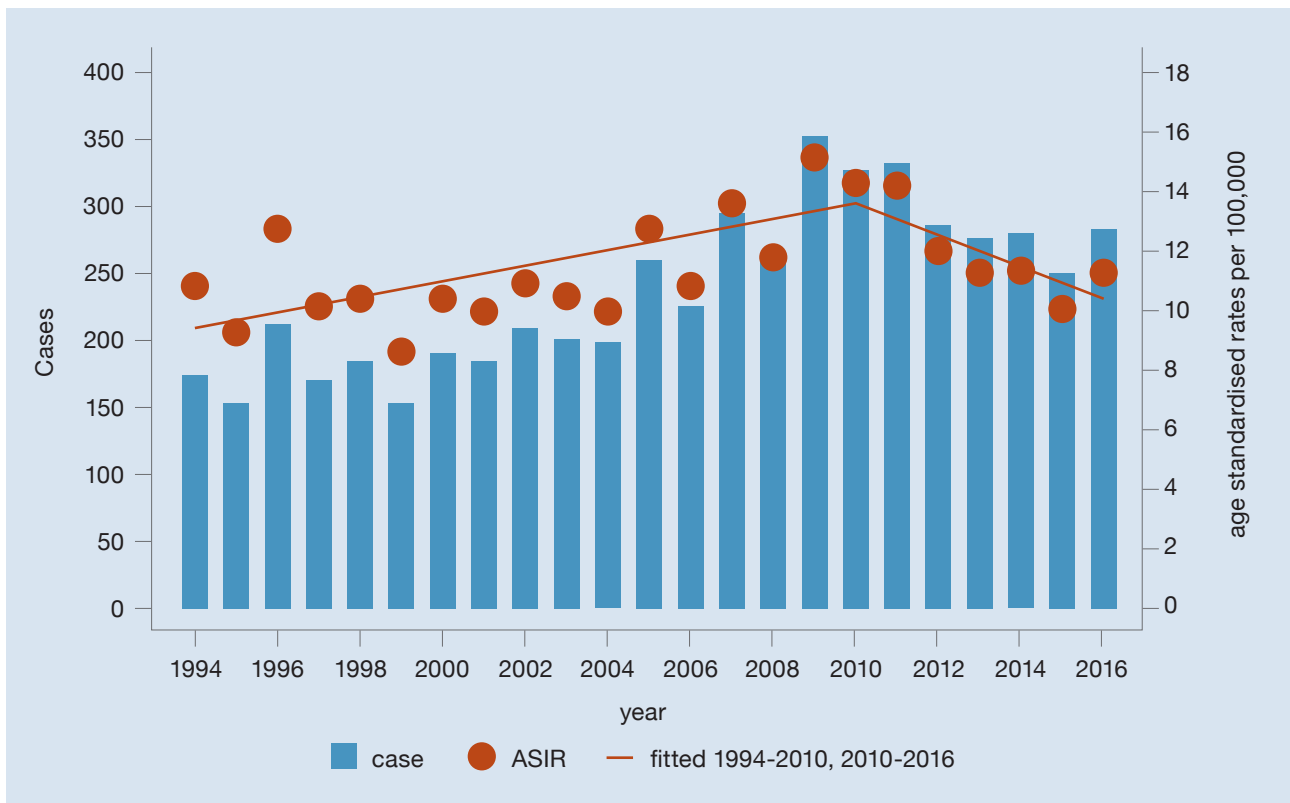
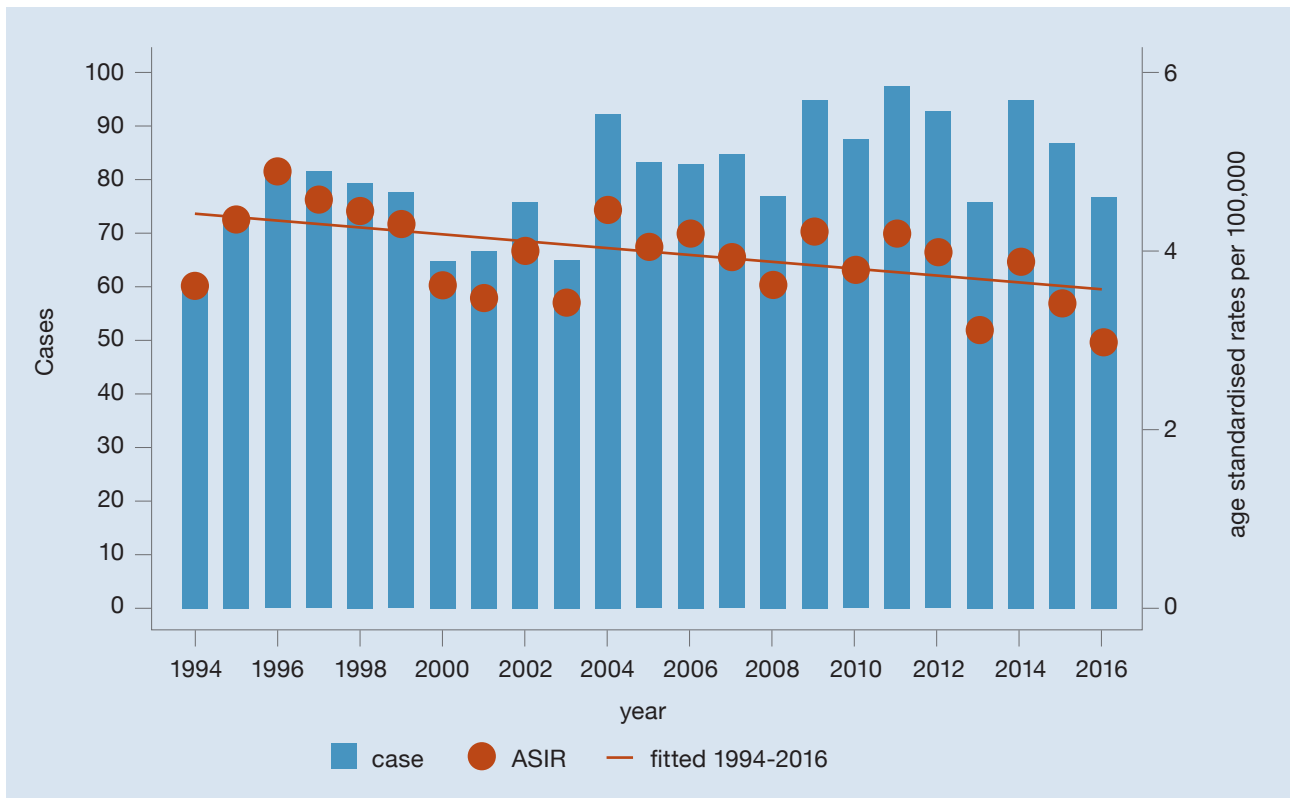


Figure 2. Trend in age-standardised mortality rate (ASMR) for cervical cancer, 1994–2016



Cervical screening in Ireland

The Irish Cervical Screening Programme Phase One began operation in the Mid-West in 2000 under the aegis of the Mid Western Health Board and, more recently, the Health Service Executive (HSE). In September 2008, CervicalCheck – The National Cervical Screening Programme became the cervical screening programme used throughout Ireland.⁽¹⁸⁾ CervicalCheck offers free screening to eligible women aged 25–65 years in Ireland. The screening programme is based in primary care and women’s health clinics, with more than 4,500 doctors and nurses registered with the programme. CervicalCheck has memoranda of understanding with 15 quality-assured colposcopy clinics located throughout the country for provision of services for further management of women who have an abnormal cervical smear at screening. These practices are based on the model of care agreed between CervicalCheck, the British Society for Colposcopy and Cervical Pathology and the Royal College of Obstetricians and Gynaecologists (RCOG).

Women on the Cervical Screening Register (a population register of women eligible to be screened) are invited to screening at regular intervals between the ages of 25 and 65 years. The Cervical Screening Register supports CervicalCheck to call and recall women for screening as appropriate. If a woman is diagnosed with cervical cancer, CervicalCheck is notified by the treating colposcopy clinic, gynaecology/ oncology clinic, or the woman’s general practitioner (GP).

The purpose of cervical screening is to identify women at risk of developing cervical cancer and to prevent cervical cancer from developing. The aim of CervicalCheck is to reduce the incidence of, and mortality from, cervical cancer in the screened population. In pursuit of these goals, CervicalCheck sets an objective to achieve a significant level of coverage of the eligible population. Coverage is defined as the proportion of unique women who have had at least one satisfactory screening test taken within the defined screening interval, expressed as a percentage of the total number of eligible women in the population.⁽¹⁹⁾ Coverage over the 5-year reporting period ending 31 August 2018 was 77.8%, declining from the previous period ending in 2017, which achieved over 80% coverage. The programme’s goal is 80% coverage over a 5-year period, and 2017 was the first time the programme achieved this target.⁽⁵⁾

During the 10-year period from 2008 to 2018, CervicalCheck carried out almost 3.2 million cervical screening tests on 1.2 million women and detected more than 64,000 high-grade cervical intraepithelial neoplasias (CINs), which are precancerous changes in the cervix, as well as more than 1,500 cancers.

Limitations of screening

The overall goal of population-based cervical screening is to reduce the incidence of, and mortality from, cervical cancer. Cervical cancer screening detects early precancerous changes in the cervix, which can be treated to prevent cancer from developing. It may also detect invasive cancer when it is most likely to be treatable and curable. Screening utilises an affordable test which is easy to administer and acceptable to women who do not have symptoms. It is not a diagnostic test, as it is not specific enough to consistently detect all early changes in the cervix. International evidence has demonstrated the low sensitivity of cervical cytology testing as a screening test. Studies indicate false negative rates of up to 55% when smear tests of women subsequently diagnosed with an interval cervical cancer were reviewed: “In spite of the excellent quality of cytology in England, a high proportion of negative cytology taken up to three and a half years before diagnosis were considered to contain abnormal cells by reviewers informed of the subsequent cancer”.⁽²⁰⁾

The main limitations of screening are the following:

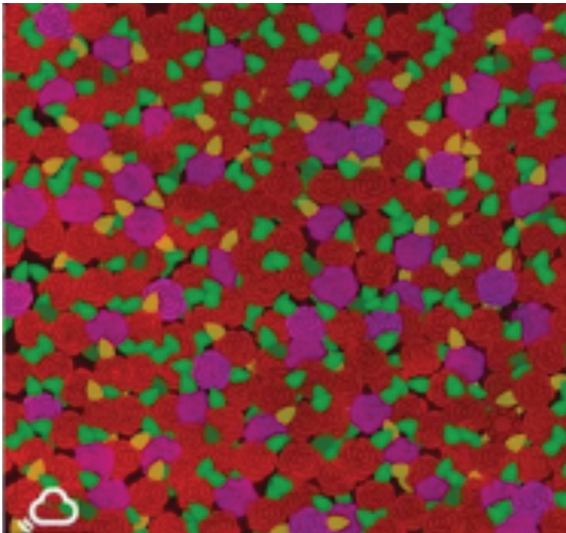
- Cervical screening will not prevent all cases of cervical cancer.
- Some women will still develop cervical cancer despite regular screening.
- Some abnormal cell changes may be missed.
- Screening will not detect every abnormal cell change.

As set out on the CervicalCheck “Important information about your free cervical screening” leaflet⁽²¹⁾, the reasons why abnormalities are sometimes missed include the following:

- Sometimes they do not look much different from normal cells.
- There may be very few abnormal cells in the sample.
- The person reading the sample may miss the abnormality (this happens occasionally, no matter how experienced the reader is).

The 2001 Bethesda system (a system of classification of cervical cytology abnormalities) requires a minimum of 5,000 cells for an adequate smear.⁽²²⁾ Cytotechnologists typically report on 40 smears per day and are expected to report on 5,000–12,000 smears annually in order to maintain competence. Figures 3 and 4 illustrate the subtle nature of these changes and the difficulty of detecting isolated changes in the midst of thousands of normal cells.

Figure 3. Schematic diagram representing the scatter pattern of normal cells



Source: Courtesy of Dr Ameli Trope, Norwegian Cervical Cancer Screening Programme

Figure 4. Schematic diagram representing a small focus of abnormal cervical cells (circled)

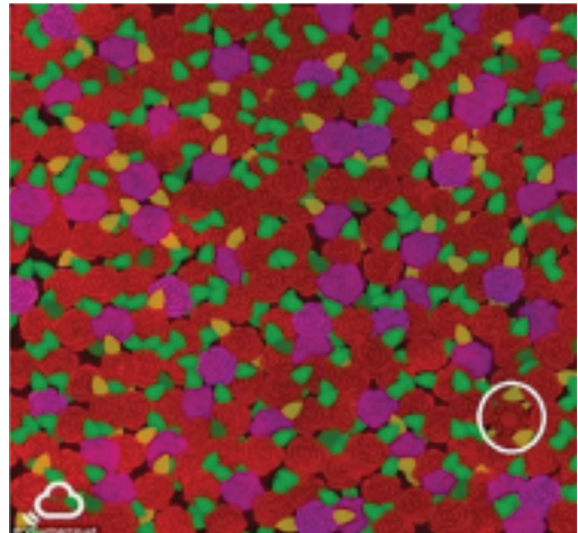


Figure 4. Schematic diagram representing a small focus of abnormal cervical cells (circled)

International evidence shows that if 1,000 women are screened using cytology:

- About 20 women will have abnormal cervical cells
- About 15 of these women will have these cells found through screening, and
- About 5 of these women will not have these cells found through screening and may develop cervical cancer.

The evolution from precancerous changes to invasive cancer typically takes at least 10 years. Thus, the sensitivity of a screening programme increases over time with repetitive rounds of screening. As abnormal cells missed on one screening test can be found on the next one, it is important for women to attend for each screening round or repeat test.

Aside from the limitations of screening, negative experiences of screening might include:

- Potential discomfort, embarrassment, or (less commonly) pain during the screening test
- Anxiety in waiting for the results, or
- Side-effects or complications due to treatment after colposcopy.

Interval cancers

An interval cervical cancer is defined as “a primary cervical cancer diagnosed in a woman after a negative screening test, but before the next invitation to screening is due, or within a period equal to a screening interval for a woman who has reached the upper age limit to attend screening”.⁽⁴⁾

It is notable that this agreed definition does not include cancers that arise as result of minimal/borderline abnormalities at the time of screening which do not warrant referral to colposcopy. After a defined screening interval, a woman will have another screening test which may have a result requiring colposcopy assessment followed by a diagnosis of cervical cancer. Thus, a cancer which has developed in the interval between a smear with borderline changes and the next smear test would not meet the strict definition of interval cancer.

Interval cancers will arise in all cancer screening programmes. Irrespective of quality assurance measures implemented to ensure the most effective and sensitive screening programme, a proportion of cancers diagnosed each year will include interval cancers.⁽²³⁾

For example, in National Health Trusts in England, a review of three years of cervical cancers diagnosed between 2007 and 2010 reported that the reviewers found that 55% of cytology specimens from all invasive cancers agreed with the original review (concordant).⁽²⁴⁾ In the subset of women with negative cytology (interval cancers), 3,759 slides were reviewed of which only 45% were concordant thus 55% had a discordant (changed) report: 11% were inadequate samples, 21% had low-grade changes and 23% had high-grade changes or worse.

Establishment of the Expert Reference Group

As a consequence of the issues that arose in CervicalCheck 2018 which related to the clinical audit of cytology in patients with invasive cervical cancers, further audit of cancers was paused. In 2019, the HSE established two Expert Reference Groups: one for BreastCheck and one for both CervicalCheck and BowelScreen. These groups were asked to “define the future audit processes and review guidance for interval cancers in the National Screening Service based on international evidence and best practice.” (Appendix 1)

The Expert Reference Groups and their respective Working Groups considered the current review practices and the patient information and consent processes, agreed the principles relating to clinical audits, and conducted two projects to determine international cancer screening practices: an international literature review and a survey of practices in established national or regional cancer screening programmes which serve a population equal to or larger than Ireland.

The Expert Reference Group has recognised the rationale to report and monitor all cancers, including interval and screen-detected cancers. The recommendations in this report focus on the following requirements:

1. The obligation to patients to provide access to all of the information related to their care, including a review of their screening history and cytology communicated in a supportive and open way, once a patient wishes to have this information and provides consent.
2. The requirement to conduct educational exercises as a key element of both the quality assurance of the programme, and of professional education and development in a manner that supports recruitment, retention and knowledge development in professional staff. This helps improve the quality of the service provided to women.
3. The necessity to develop a key performance indicator (KPI) for the programme’s interval cancer rate in order to benchmark the rate internationally.
4. The programme must be affordable within the challenging environment of demand for all health services. Cancer screening must be sustainable in order to achieve the benefits of reducing the incidence and mortality of cervical cancer in the screened population.

The specific objectives are to:

1. Consider which individual screening programmes are currently reporting against international best practice
2. Determine best internationally accepted processes for reviewing and reporting interval cancers, and
3. Develop, in line with National Standards for Clinical Practice Guidance Development⁽²⁵⁾, operational guidance which sets out the principles and processes for how audits and individual case reviews should be undertaken following a diagnosis of interval cancer in the screened population. This guideline should:
 - 3.1. Establish standardised informed consent processes
 - 3.2. Outline the future method of audit in such situations in Ireland, such that cancer screening programmes may be assessed with regard to their operation within agreed standards
 - 3.3. Outline the future method of individual case review in such situations in Ireland
 - 3.4. Consider the data protection requirements which will be necessary for the implementation of the proposed systems of audit and individual case review

- 3.5. Take account of current and planned legislation around open disclosure and make recommendations regarding disclosure of the results of audit and/or individual case review to individual service users
- 3.6. Propose recommendations on communication processes and timelines
- 3.7. Outline any ethical implications that the proposed systems of audit and individual case review may have for patients, the general public, healthcare professionals or the health system, and
- 3.8. Outline any organisational implications, including the impact on long-term sustainability that the proposed systems of audit and individual case review may have on the National Screening Service and its individual screening programmes.

The full terms of reference are included in Appendix 1.

Guiding Principles for Clinical Audit

In accordance with the Clinical Audit of Interval Cancer in the Screened Population Terms of Reference, the CervicalCheck/BowelScreen Expert Reference Group and its respective Working Groups agreed on the following principles:

1. Population screening refers to a test that is offered to all individuals in a target group (usually defined by age) as part of an organised programme, with the overall aim of prevention or early detection of the disease and thereby reducing mortality from the disease in that population. Well-organised and systematically conducted screening, with rigorous internal and external quality control, is effective at the population level and must continue to be offered to the eligible public in Ireland.
2. In line with the Wilson and Jungner criteria,⁽²⁶⁾ which state that the cost of case-finding (including diagnosis and treatment of diagnosed patients) should be economically balanced in relation to the possible expenditure on medical care as a whole, the recommendations of our Expert Reference Group should not jeopardise the overall cost-effectiveness of screening programmes.¹
3. The purpose of clinical audit in screening programmes is quality assurance and quality improvement (professional education and development) in order to provide rigorous internal and external quality control.
4. Within each screening programme, an evidence-based definition of an interval cancer must be clearly defined.
5. The rate of interval cancers in each screening programme should be determined using a defined numerator and denominator.
6. Public and stakeholder information and communications regarding the audit processes must be informed by international practice.
7. Public and stakeholder information must clearly state the benefits and limitations of population screening programmes.
8. Communications with patients diagnosed with invasive cancers must be respectful and open, reflecting the HSE values of care and compassion.

¹ Cost-effectiveness analysis (CEA) is defined as an analytical technique intended for the systematic comparative evaluation of the overall cost and benefit generated by alternative therapeutic interventions for the management of a disease.(WHO Guide to Cost-Effectiveness Analysis, 2003)

Ex. A-10

9. Recommendations for future clinical audit of interval cancers should be informed by international practice.
10. A standardised, reproducible approach to clinical audit must be established for each screening programme.
11. For the purpose of this work, the clinical audit of interval cancers should focus on two different circumstances:
 - a. Planned programmatic reviews as part of a quality assurance process in order to identify areas of improvement, action and implementation, and
 - b. Individual case reviews.
12. Acceptable facilities and resources to conduct the clinical audit of interval cancers should be available.

Section Three: Current Practice in the Cervicalcheck Screening Programme

Quality assurance in the CervicalCheck screening programme

The quality assurance requirements and standards for the cervical screening programme are based on European guidance, as set out in the *European guidelines for quality assurance in cervical cancer screening: Second Edition* ⁽⁶⁾ and the *CervicalCheck Guidelines for Quality Assurance in Cervical Screening: Second Edition*.⁽²⁷⁾ KPI data are reviewed in several levels of detail at a number of forums and published annually. They are grouped under the principal components of the cervical screening pathway: programme operation, primary care/smear taking, cytopathology, human papillomavirus (HPV) testing, colposcopy and histopathology. The process is governed via the National Screening Service Quality Assurance Committee for Cervical Screening, which reports to the CervicalCheck Senior Management Team.

Governance structures for Quality Assurance, including oversight of key performance indicators and audits, are well established within the screening programme. Details can be found in Appendix 3. All screening programmes report to the Chief Executive Officer of the National Screening Services who is accountable to the Chief Clinical Officer of the HSE.

Key performance indicators

Three distinct groups of indicators are identified in the *CervicalCheck Guidelines for Quality Assurance in Cervical Screening: Second Edition* ⁽²⁷⁾:

1. Screening intensity, which is the proportion of the target population actually screened within the recommended interval
2. Screening test performance indicators, which include the referral rates for repeat cytology and colposcopy; colposcopy outcomes; and rates of detection of CIN
3. Diagnostic assessment of treatment indicators, which include compliance with referral for repeat cytology and for colposcopy. The treatment of high-grade lesions is also an essential KPI.

Audit of interval cancer

Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.⁽¹⁾ In Ireland, where cervical screening is a relatively new programme, an audit of cytology in all women known to be diagnosed with invasive cancers in the first 8 years of the programme (1,482 cases, of which 1,296 had participated in CervicalCheck) was undertaken. In 221 cases, the cytology review reported discordance with the original smear test report. Results of the changes in cytology were ultimately communicated in writing to the doctors involved in each patient's care, but communication with patients frequently did not occur. These issues came to light in 2018 and caused a crisis in confidence in the CervicalCheck programme, which has been well documented in the *Scoping Inquiry into the CervicalCheck Screening Programme*, conducted by Dr Gabriel Scally and commissioned by the Minister for Health, and which was published in September 2018.⁽⁷⁾ Despite his comment on the laudable intentions of the audit, Dr Scally's report found a wide range of issues which needed to be addressed, including the processes of review. The report was critical of the audit process, particularly of the fact that the women involved were not informed of this audit and that the HSE Open Disclosure Policy was generally not followed. This report also highlighted examples of poor communication with the women affected and their families. The recommendations of Dr Scally's report are now being implemented, including disclosure to patients or their next of kin.

Open disclosure in CervicalCheck

CervicalCheck disclosed the outcomes of its audit of invasive cancers in a manner that caused considerable distress to those affected.⁽⁷⁾ The outcomes of the subsequent RCOG review in the United Kingdom (UK) was published on 3 December 2019.⁽²⁸⁾ Patients who participated have already been notified of their results and were offered individual meetings to discuss the findings. These meetings are now in progress.

Section Four:

International Practice

International evidence was assessed by reviewing the published literature, investigating best practice from the perspective of international cervical screening experts and conducting a survey of international cervical screening programmes.

Literature review

Method

A search strategy for English-language articles published up to May 2019 was developed and conducted in accordance with the Populations, Interventions, Comparators, Outcomes, and Study types (PICO) approach. The databases Scopus, Google Scholar, CINAHL, Web of Science, Embase, ScienceDirect and Global Health were searched.

In addition to the peer-reviewed literature, the websites and publications of international cervical screening programmes were accessed.

The literature review addressed the following questions:

1. What is the approach to the audit of interval cancers in cervical screening programmes?
2. What processes are in place for the audit of interval cancers?
3. What is the approach to disclosure with regard to the outcome of audit of interval cancers in the screened population?

A total of 33 documents were deemed relevant for appraisal by the CervicalCheck Working Group. The Working Group used a specifically adapted version of the MiChe Rapid-Assessment Appraisal Tool ⁽²⁹⁾ to assess the systematic quality and applicability of all the literature and guidance documents reviewed. This validated assessment instrument was considered appropriate for use by the Working Group.

More than half of the documents reviewed (n=17) were published in peer-reviewed journals. Policies and standard operating procedures from international screening programmes which were accessible online were also reviewed.

Appraisal of the 33 documents was carried out by 14 Working Group members (Appendix 4). Of the 33 documents appraised, 32 were determined to be relevant by the Working Group.

Findings

The literature review identified that there are variable approaches to audit and disclosure of interval cancers in cervical screening programmes, and therefore no international consensus on what constitutes best practice.

What is the approach to audit in cervical screening programmes?

The literature review identified various approaches to the elements of the cervical screening process that are audited. In some studies the focus was on administrative processes, such as attendance, call, and recall (e.g. Sweden), which provided evidence that the incidence of interval cancer is inversely related to programme participation rates. Considerable work has been undertaken to audit invasive cervical cancer in the National Health Service (NHS) England Cervical Screening Programme. Audits covering the time period from 2007 to 2013, published in two separate reports, reviewed cytology and histology and are discussed in this section under consultations with international cervical screening programmes. ^(20, 24)

Approach to audit of interval cancers

There are very few publications with regard to the audit of invasive cancers. All of the research and publications reviewed were undertaken for the purpose of quality assurance and education. Four publications reported reviews of cytology of screening participants diagnosed with invasive cervical cancers. ^(12, 20, 24, 30)

Publications related to the review of cytology and histopathology as part of the NHS England Cervical Screening Programme's audit of invasive cervical cancers found that between April 2007 and March 2010, 6,113 women were diagnosed with cervical cancer. Of 13,745 cytology results from women who developed cervical cancer, 55% were reviewed.

The findings were concurrent for more than half (55%) of the slides reviewed. ⁽²⁴⁾

Analysis of 3,759 slides originally considered to be normal (interval cancers) yielded different results on review, with only 45% being determined as "normal" on review; 55% (n=2,068) were changed for the following reasons:

- Eleven per cent were found to have an inadequate sample on the original slide.
- Twenty-one per cent were found to have low-grade changes not recognised on the original slide.
- Twenty-three per cent were found to have high-grade changes not recognised on the original slide.

A later paper published by the same team in 2014 found discordances in both the histology and cytology of 8,784 women who had a confirmed diagnosis of cervical cancer between April 2009 and March 2013. Almost half (47%) of the cases diagnosed in women aged 25–49 were microinvasive cancers (stage 1A); 36% were stage 1B. However, in women aged 50–64, 49% of cancers were stage 2 or higher. Concordance between the original result and the review result was 59% for cytology and 90.2% for histological samples. This shows an improvement in concordance for cytology since the report that was published in 2012. ⁽²⁴⁾

After the literature review concluded, Public Health England (PHE) published its most recent quality assurance audit in October 2019.⁽¹⁰⁾ It reported on the 2013–2016 period and, in an unblinded audit of cytology, demonstrated that the previously negative findings in patients aged 25–49 who had interval cancers were upgraded in 42% of cases. These publications on NHS England's cytology reviews are the key evidence of the limitations to the smear test's accuracy.

What is the approach to disclosure with regard to the outcome of audits of interval cancers in the screened population?

Despite well-documented, longstanding knowledge of false negative and highly discordant findings on audit of cytology, few publications discuss disclosure.

Two UK screening programmes (England and Wales) provide operational guidance on disclosure. Other international programmes have not published such guidance.

Our review identified one 2015 study in England which preceded Duty of Candour legislation but followed the introduction of an open disclosure policy. The study found that despite National Cervical Screening Programme guidelines, only 53% of all responding clinicians offer review meetings to patients and those that did offer meetings did not offer them to all patients.⁽¹¹⁾ For the 47% of respondents who did not offer review meetings, the reasons cited were: lack of awareness of guidelines; time constraints; fear of causing distress; and, rarely, fear of litigation. This was consistent with a 2012 study⁽¹²⁾ that found low rates of disclosure.

Survey of international cervical screening programmes

Methodology

A formal survey was undertaken by the Expert Reference Group, the CervicalCheck Working Group and the Programme Evaluation Unit within the National Screening Service to gather information from international population-based cervical screening programmes on their processes for the audit and review of interval cervical cancers.

We contacted well-established international cancer screening programmes across Europe, Canada and Australia, all of which provide comprehensive access to all eligible members of the public in jurisdictions with populations similar to or greater than Ireland's population of 4.8 million, with one exception: we consulted Northern Ireland (population 1.8 million), as it is the NHS jurisdiction geographically closest to Ireland. The survey was circulated to 22 screening programmes in May 2019. If no response was received, the contact was repeated three times. If responders required any clarification about the survey, the National Screening Service responded to all of their questions. Globally, many countries and regional jurisdictions do not have comprehensive, publicly funded cancer screening programmes, and thus were not eligible to participate.

Results

Seventeen countries/regions out of 22 countries invited completed the survey, giving a response rate of 77%. Of the 17 countries/regions that completed the survey, 11 have an audit process in place for interval cancers; the remaining 6 countries/regions do not have an audit process for interval cancers.

Summary of key points of the international survey

The main findings of the survey are as follows:

- Seventeen of the 22 countries/regions contacted responded to the survey (77%).
- Eleven of the 17 responding programmes have an audit process in place for invasive cervical cancers, while the remaining 6 countries/regions do not have an audit process.
- Of the 11 countries/regions that carry out audits, reviewers in 3 countries/regions are not aware of the cancer diagnosis, i.e. they are blinded when reviewing the slides of an invasive cancer.
- All of the screening programmes carrying out audits differed in their approaches.
- Of the 11 countries/regions that carry out audit of interval cancers, 6 have an open disclosure policy for medical incidents. Of these, four countries/regions have a mandatory open disclosure policy for medical incidents in place.
- Of the six countries/regions that have an open disclosure policy for medical incidents, three countries/regions have an open disclosure policy that applies to invasive interval cancers in screening.
- Of the 3 countries/regions that have an open disclosure policy that applies to screening, it was confirmed through subsequent interviews with these jurisdictions that one region contacts patients directly, while the other two jurisdictions write to the patients' treating clinicians advising disclosure. Since the completion of this survey, a fourth region has signalled intent to implement open disclosure.
- Three countries/regions have legislation protecting clinical audit from disclosure to patients.

The questionnaire and its results are detailed in Appendix 2.

Conclusion based on the international survey

The respondent countries/regions do not have a consistent approach to audit of invasive interval cancers or to disclosure. Two countries have adopted an approach of full programmatic review and recommend disclosure to the patient, while a third country conducts cytology review only and recommends disclosure. Jurisdictions elsewhere typically do not disclose the results of audits to patients, as the audits are considered to be quality assurance and educational exercises. In some countries/regions, there is legislative protection from disclosure of clinical audit results.

Consultations with international cervical screening programmes

In order to further investigate international practices, the Expert Reference Group consulted international cervical screening experts to discuss their approaches to clinical audit of invasive cancers and disclosure. These approaches are summarised below.

Norway

- Norway (population 5.3 million) has had the Norwegian Cervical Cancer Screening Programme in place for women aged 25–69 since 1995. The screening interval is every 3 years.
- Cervical cytology testing is conducted in 15 hospital laboratories and 2 private laboratories.
- Norway has commenced implementation of primary HPV testing, which is now offered to 30% of women attending screening, according to regional roll-out. Primary HPV testing is conducted every 5 years.
- 1,030,915 women were screened within the last 3 years.
- The Norwegian laboratories routinely re-screen previous smears when identifying a patient with High Grade Squamous Intraepithelial Lesion (HSIL) or Cervical Intraepithelial Neoplasia 2 (CIN2). Since smears may have been evaluated at different laboratories (due to the patient moving or changing doctors), there was a need for a national audit.
- National laboratory audit of cervical screening in Norway has been in place since 2013. All laboratories conduct their own audits.
- Audit is done primarily as a quality assurance measure for the programme and to drive improvements in the system. Audit is not mandatory, but a protocol and a list of cancer cases with cytology up to 5 years (before showing normal, atypical squamous cells of undetermined significance (ASCUS), low-grade squamous intraepithelial lesion (LSIL), or unsatisfactory smear) and benign histology is shared with all laboratories. Only a laboratory audit of smears and histology is undertaken. This audit is blinded with two controls per case. All laboratories have now participated.
- Since 2016, there is also a national central audit of smears and histology. The National Central Audit Group consists of pathologists and cytology screeners. The results from the National Central Audit Group overrule the local decision if two-thirds agree on a diagnosis. There is a continuous evaluation of whether there is a need to continue with the audit.
- If there is a change in diagnosis to a high-grade cytology and histology, the laboratory informs the gynaecological department following up with the cancer patient, or the smear taker who took the smear, about the revised result.
- When a physician is notified that a patient with cervical cancer has had a change in cytology from normal (interval cancer), ASCUS (a common early finding), or LSIL (mild dysplasia) to a high-grade change or cancer, the physician is expected to discuss this with their patient. There is not yet a standardised letter to doctors or patients (this is being developed), nor is there standardised documentation to confirm that the patient has been notified.
- Women are not automatically compensated, but they can contact the Norwegian System of Patient Injury Compensation to make a claim, in which case a third level of independent audit is undertaken. If there is compensation, the laboratory maximum is €10,000.

- In a previous case in 2017, it became apparent that laboratories did not have access to the whole screening history in relation to individual women, or to information about individual women. In 2019, all laboratories were granted access to all screening results, histology results and treatment information.
- Screening professionals in Norway have worked closely with journalists to increase awareness around screening issues and acknowledge the challenges associated with screening.

British Columbia

The British Columbia Cancer Agency (BCCA) provides cervical cancer screening (cytology) every 3 years for women aged 25–65. Prior to 2016, screening was initially recommended annually, and then changed to every 2 years; until international evidence indicated that a 3-year screening interval was equivalently safe. In Canada (population 37 million), health services are the responsibility of each provincial government. Nine of the 10 provinces (population 28.5 million) have population-based cervical cancer screening programmes. British Columbia (population 5 million) has one of the oldest cervical cancer screening programmes in the world, which has been operational for more than 50 years.

- In the 50-year duration of the programme, the incidence of cervical cancer in British Columbia has declined by 70% and mortality has declined by 75%.⁽³¹⁾
- The BC Cancer website states that screening reduces the risk of being diagnosed with cancer by up to 70% and that if cancer is caught at an early stage, the chance of survival is greater than 85%.⁽³²⁾
- Likewise, for the nine provinces offering screening, the incidence of cervical cancer fell from 13 per 100,000 female population to 3 per 100,000 between 1984 and 2015.
- At least 70% of eligible women participate in screening in British Columbia.
- Information is available to women online and through leaflets in GPs' offices. Information regarding protection of privacy and personal information is included. Women are advised that their personal information may be used for quality assurance.
- Consent is implied by participation in the programme.
- Cytology results are sent to GPs' offices; however, since 2019, women have been able to read their own results online.
- Each year some 350,000 cytology tests are read in a single, dedicated BCCA laboratory.
- In addition to mandatory (according to Canadian and American standards) laboratory quality assurance of routine cytology, the BCCA laboratory conducts an internal audit of the previous 5 years of cytology results on all diagnosed cancer cases (180 patients in the most recent year) on an ongoing basis.
- The cytology review is blinded (on a 1/1 basis). Patients who have never been screened or who have not had a screening in the previous 5 years are excluded from review.
- Quarterly reports go to each cytotechnologist and supervisory cytopathologist.
- Teaching slide sets are available for cytotechnologists and pathologists and are discussed at teaching rounds.

- In British Columbia, provincial legislation protects quality assurance and audits from disclosure to patients, except in circumstances where their current disease management might change. In the setting of patients already diagnosed with and treated for cancer, there would be no change in management, and thus there is no disclosure.

Of note, each of the nine Canadian provinces engaged in cervical screening has legislation protecting audits from disclosure. This protection applies generally in health services and is not specific to public health programmes such as screening. The legal protection was established to improve the focus on quality assurance and education for professional staff.

Netherlands

- The Dutch National Cervical Cancer Screening Programme is one of seven screening programmes in their Centre for Population Screening, which are all coordinated by the Dutch National Institute for Public Health and the Environment (RIVM), an agency of the Ministry of Health, Welfare and Sport.
- The Centre for Population Screening sets standards and governs quality assurance and implementation of programmes. It commissions services nationally, which, for cervical screening are delivered in 5 regions.
- Cervical cancer screening in the Netherlands (population 17 million) is a preventative screening programme for women aged between 30 and 60 years. Cervical smears were collected and used for diagnostics and screening on a large scale in the Netherlands since 1970. Since 1996, a nationally standardised population based screening programme has been applied. Cytology was performed in 40 hospital laboratories and was the primary screening test until January 2017.
- The Netherlands was one of the first countries to introduce HPV testing as the principal screening modality in January 2017. The screening interval is every 5 years, changing to every 10 years for low-risk women.
- The Netherlands is in the process of developing a quality assurance and audit programme, including interval cancers, for the future. HPV tests are not available for retrospective audit. Testing has been centralised to five laboratories.
- There is a comprehensive national histopathology registry, including cytology. Hospitals can access their own data and request screening data from other laboratories. All hospitals register cervical cancers in the screened population in PALGA: Dutch Pathology Registry. PALGA is the nationwide network and registry of histo- and cytopathology in the Netherlands.
- Prior to the commencement of HPV testing, if an interval cancer is diagnosed, the hospital reviews its own cytology or slides from another hospital on request.
- If an interval cancer is detected, the screening laboratory will review its own slides. The review of cytology in the context of quality assurance is internal to the hospital and is not anonymised or blinded. This presents a risk of retrospective bias. Notification is included in the PALGA report by means of a disclaimer. The modified report is sent to the GP. If a discrepancy is noted on cytology review, it is notified to the National Cervical Cancer Screening Programme, as well as hospital risk management personnel.
- If a discrepancy noted on cytology review has clinical consequences for the patient, the reviewer must ensure that the GP is aware of the changed report.

- The internal reviews are for professional development and quality assurance; they are not disclosed to the patient by the screening laboratory.
- If an individual cancer patient requests a review, it is policy that the attending physician must request this review. In that case, an anonymised and blinded review of cytology is carried out among 10 independent pathologists.
- There is no legislation mandating open disclosure to patients. The responsibility lies with the care provider in question, based on his or her duty of care.

England

In England (population 56 million), the National Cervical Cancer Screening Programme was established in 1988. In their governance structure, Public Health England (in compliance with advice from the UK National Screening Committee) is responsible for provision of standards and guidance to service providers and their commissioners, quality assurance, data analysis, incident management advice and public information. England operates a distributed model of cervical screening: NHS England and NHS Improvement commissions service providers in 7 regions, including GP Practices and Hospital Trusts (132) that provide laboratory (HPV testing, cervical cytology and/or histology) and colposcopy services. NHS England and NHS Improvement also commissions the national call and recall administration service (CSAS).

- The local Hospital Trusts are accountable for delivery of laboratory and colposcopic services and their related audit and internal quality assurance, in compliance with national guidelines. Hospital Trusts are responsible for patient communications and disclosure relating to the cervical invasive cancer audit.
- CSAS is responsible for inviting, reminding and issuing result letters to eligible women.
- There were 49 laboratories providing cytology, this number has recently reduced to 8 laboratories following the implementation of HPV Primary screening. These 8 services provide both HPV and cytology.
- Primary HPV screening was implemented by NHS England and NHS Improvement in December 2019, after 4 years of planning.
- Colposcopy is conducted in about 200 centres. The majority of the 132 Hospital Trusts providing colposcopy services will also have local cervical histology laboratory services
- A local Cervical Screening Provider Lead (CSPL) has oversight of each Hospital Trust's cervical screening service. The CSPL coordinates invasive cancer audit data from each Trust and reports it nationally to PHE's Screening Quality Assurance Service (SQAS) for national analysis. The CSPL coordinates arrangements to ensure women are offered results of the audit if they wish to receive them
- Hospitals identify newly diagnosed cases of invasive cervical cancer from colposcopy clinics, Multidisciplinary team conference records or histology data
- Separately, national data is available from the Cancer Registry to cross check with national SQAS records.
- Since 2007, all cases of invasive cancer have been reviewed whether or not the individual participated in screening (legal approval in place).

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- More than 2,500 cancers are diagnosed annually. The review of cytology, histology and colposcopy is conducted by the local service multidisciplinary team.
- Public Health England publishes online cancer audit guidance. An audit management committee with representation from all parts of the screening pathway advises on development of the audit.
- Cytology review of all cases of invasive cervical cancer is internally conducted by the original laboratory.
- Slides are part of a continuous review process and are not batched. According to criteria, some slides will be selected for further external review by one of the 4 cytology training schools in England.
- Reviews are NOT blinded. Laboratory experts in England believe that the work load and organisational issues involved in blinded reviews are impractical and do not answer the relevant question. The reviews are undertaken to identify any potential reasons why a cancer may have subsequently developed to inform the development of the national programme and provide information to women. The reviews are not intended to try and answer a historical question of whether routine screening would have identified an abnormality at the time of primary screening.
- The principal purpose of cytology review is educational.
- Since 2001, all women are told that an audit will take place and they will be offered disclosure of its findings. It is the responsibility of each Trust to communicate this information, either in locally developed contact letters or when the oncology nurse meets a new patient. Disclosure, if the patient consents, is carried out by local providers.
- Nationally, the SQAS team does not routinely collect data on disclosure meetings at present. The process is picked up as part of routine QA visits, which take place at least once every 5 years for each Trust, the QA team checks whether appropriate audit and disclosure arrangements are in place
- In some cases, reviews can take more than 12 months to complete. The cytology review is the most time consuming. New guidance is in development with an aim to reduce timelines to a maximum of 12 months.
- Guidance on disclosure for the cervical screening programme along with training questions and a teaching video and national patient information materials on open disclosure are currently in development.
- Public Health England publishes Invasive Cancer Audit Reports every 3-5 years. These are an excellent source of information on all elements of audit. The most recent report on patients diagnosed between 2013 and 2016 was published in 2019. It reported that for patients aged less than 50, within 3.5 years of diagnosis, 20% had a negative test, which, on non-blinded review, was upgraded to borderline or worse cytology in 42%. This meant that 8.5% of patients with cancer had a test where an abnormality was not identified by routine screening. For patients aged over 49, 27% had a negative cytology test within 5.5 years of screening, 46% of these were upgraded to borderline or worse on review, meaning 12.5% for whom routine cytology did not identify an abnormality.
- Overall, in the total diagnosed with invasive cervical cancer (2,591 in 2017, Office for National Statistics), and the much greater numbers of well women screened in England (3.18 million, NHS Digital and Public Health England), these numbers are very small.

Wales

- Cervical Screening Wales (currently as part of Public Health Wales NHS Trust, previously as Velindre NHS Trust) has provided national cervical cancer screening since 1999. The overall population is 3.14 million individuals. Approximately 230,000 screening invitations were sent in 2018-2019, and 175,000 tests performed. Initially, cytology was the primary screening test, reported in 15 laboratories. HPV testing was introduced in a phased manner between 2014 and 2016, initially as 'Test of Cure' and then as triage of low grade abnormalities.
- Since October 2018, primary HPV testing has been implemented as the initial test following an 18 month 'early adopter' phase. Now, a single laboratory is responsible for both HPV and reflex cytology processing. Pathologists in several regions across Wales participate in reporting and auditing cytology using an all-Wales network. One pathologist is the senior quality assurance clinician for the cervical screening programme.
- Wales has an excellent integrated IT system linking colposcopy, cancer diagnosis and management, histopathology in hospitals, cytology and screening data. This provides prompt information on newly diagnosed invasive cervical cancers and facilitates audit.
- The national Clinical Lead for cervical screening reviews all newly diagnosed invasive cancers monthly and ensures that the audit processes are initiated.
- Formal, standardised audit of cytology began in 2009 and is based on protocols published by Public Health England. Audits of cytology currently necessitate review of legacy slides (both SurePath and ThinPrep) up to 10 years ago, from laboratories no longer performing cytology screening. Review is not blinded. A network of pathologists and consultant biomedical scientists who are involved in multidisciplinary team meetings and in reporting cytology have an oversight role in audit. The principal aim of the audit is educational. The reports of the audit do not go back to the original cytotechnologist. The senior biomedical scientist conducts teaching sessions based on the audit findings and other interesting/educational cases every 2 weeks.
- Each case review includes scrutiny of the screening, histopathology, administrative and colposcopy information. Public Health Wales (PHW) commissions colposcopy services from the seven Health Boards within Wales. There are 16 colposcopy clinics between 7 Local Health Boards. PHW monitor colposcopy waiting times. Five Health Boards report the histopathology on colposcopic biopsies. The Clinical Lead reviews any colposcopy episodes between 18 weeks and 5 years prior to the diagnosis of invasive cervical cancer. The review checks whether the colposcopy was timely in relation to the urgency of the smear test and whether the management was satisfactory on the day of attendance. Colposcopy is rated as: satisfactory, satisfactory with learning points or unsatisfactory. The Clinical Lead reports the results to the lead colposcopist of each health board.
- There are at least monthly colposcopy multidisciplinary team meetings which may be conducted via videoconference across Health Board areas. There are strict guidelines on eligibility for discussion and attendance.
- Once the review of each case is finalised, the Screening Programme Clinical Lead writes to the relevant clinician involved in the patient's care to advise that either:
 - a) No change on review. The Screening Programme is open to a meeting.
 - b) Issues may be identified (e.g. change in cytology) but no delay to diagnosis or change noted in management. A letter is sent advising that there is no change to management. A meeting is offered.
 - c) Issues identified which would have affected management and may have led to a delay in diagnosis. A letter is sent advising that the results are available. A meeting is offered.

Cervical Screening Wales does not give the results directly to the clinician, as the Programme leadership believe that the disclosing clinician needs a very good understanding of the screening process and limitations of screening, to be able to answer any questions from the participant.

Cervical Screening Wales does not directly contact the patient; this is expected to be done by the treating clinician who is responsible for advising/recommending a meeting with Cervical Screening Wales.

Cervical Screening Wales does not document whether or not the clinician informs the patient about contacting the Programme for a meeting.

The participants in screening are provided with information about audit and disclosure on the Cervical Screening Wales website. A leaflet has been produced for participants who have a screening review, to help them decide whether they wish to know the results of the review.

- If a patient requests a meeting, this is typically conducted by two senior staff from Cervical Screening Wales, typically the Clinical Lead and the Head of Programme. Alternatively, one of the 6 Programme Lead Nurse Specialists may participate. Typically, there are between 6 and 8 disclosure meetings annually. A structured approach to disclosure has been developed. Patients are sent a leaflet in advance of the meeting. Consent is implied by participation in a meeting.
- Prior to the disclosure of review results meeting with the screening participant, each case is discussed at Cervical Screening Wales Audit of Cervical Cancer Multidisciplinary Team (CSWACC MDT) meeting. This involves the Clinical Lead, Head of Programme, Legal & Risk Advisor, Cytology reviewers and QA Colposcopist (where required). This meeting is to categorise whether original reports were satisfactory or unsatisfactory, and whether there has been any apparent Breach of Care, so that there is an agreed approach to the disclosure meeting. Where there is a change on review that would have affected management, but this is not felt to be Breach of Care, the options of the 'Putting Things Right' process can be offered in the disclosure meeting.
- A cancer case review group is held on a quarterly basis. This group is chaired by the Cervical Screening Wales Clinical Lead. All cases requiring any reviews are discussed, and the review outcomes noted. Cases leading to reports for Lead Colposcopists and any disclosure/legal cases are also discussed.

Northern Ireland

At the time of conducting the international survey, Northern Ireland (population 1.8 million) was not conducting open disclosure following an audit, but was developing the processes to facilitate this. Following significant work over a 2-year period, this process has now progressed to the implementation stages.

As part of the review of evidence to inform the future of cervical cancer audit in Ireland, the Expert Reference Group asked for the cervical screening lead from Northern Ireland to present on the approach to auditing cervical cancers and to disclosing audit results. The following is the key learning from that presentation:

- In Northern Ireland, the proposed audit will involve a standardised audit of all invasive cervical cancers.
- A statement on audit is being added to the information leaflet for participants in all cancer screening programmes, and to a specific information leaflet for women diagnosed with cervical cancer to inform them that their case will be reviewed.
- There is a multidisciplinary approach to audit which considers the whole screening pathway. Cases of invasive cervical cancer are identified at hospital level and discussed at multidisciplinary team meetings. Each hospital in Northern Ireland has a hospital based programme coordinator (HBPC) who will be responsible for triggering the audit process. This audit process will be undertaken in conjunction with the cervical screening programme leads in the Northern Ireland Public Health Agency.
- The audit data set will include cytology review, colposcopy review and histology review.
- In terms of cytology review, external cytology review will be undertaken if deemed appropriate. The external review panel is selected by the Public Health Agency (the agency responsible for coordination of all screening programmes in Northern Ireland). The results of the external review will be returned by the external panel directly to the HBPC, who will record it in the audit database.
- Three key questions will be applied to the interpretation of issues arising from the audit. These questions focus on process, interpretation and impact.
- The audit outcome category will be agreed by the multidisciplinary team and assigned to every case. There are three potential audit outcome categories for invasive cervical cancer, as follows:
 - Category 1: Satisfactory review. No untoward findings.
 - Category 2: Satisfactory review with learning points. These include false negative cases or minor process or management shortcomings considered to be within the limitations of the screening programme.
 - Category 3: Unsatisfactory review, which demonstrates significant false negative changes in cytology or significant process or management shortcomings that constitute a patient safety incident.
- Cases assigned to Category 3 will invoke Northern Ireland and Trust governance procedures.
- Disclosure of audit results will be standard. However, consideration will be given to where a patient has indicated that they do not want to know the findings of the audit. A woman can change her mind at any time. Otherwise, the following approach will be followed:
 - For Category 1 patients, the patient will be written to or told the outcome at her next appointment with her consultant.
 - For Category 2 patients, the patient should be informed in writing or at her next appointment. Some clinicians may wish to offer these patients an opportunity to discuss the findings in further detail.
 - For Category 3 patients, the woman should be written to, advising that the results of the audit are now available, and offered an appointment to discuss the findings with her consultant.

Ex. A-10

- The multidisciplinary team at Hospital Trust level will agree who is best placed to meet with the patient, taking account of the nature and complexities of the issues to be discussed. The meeting will always be led by an individual with whom the patient already has a relationship. Full disclosure will be given to all patients at the meeting.
- The target timescale for completion of the audit of cervical cancers is within a maximum of 6 months of the diagnosis of cancer.
- Monitoring compliance: Each hospital will be expected to undertake an annual audit of its compliance with the audit and disclosure pathways. These will be monitored at annual quality assurance data review meetings for cytology and colposcopy with the Public Health Agency and the Northern Ireland Quality Assurance Leads.

Scotland

Background

Cervical screening was introduced in Scotland (population 5.45 million in 2019) in the 1960s. Although large numbers of women were offered tests, the service at this time was not introduced as a population based programme. The national cervical screening programme was introduced in Scotland in 1988 with the aim of reducing the incidence of invasive cancer of the cervix by identifying cell changes which may develop to be pre-cancerous in women who otherwise have no symptoms. These cell changes can be easily treated and treatment is usually very effective. Initially women aged 20-60 years were routinely invited every three years. Women on non-routine screening (where screening results have shown changes that require further investigation/follow up) were invited up to the age of 68. From June 2016, the age range for cervical screening changed from ages 20-60 years, to ages 25-64 years plus 364 days. The frequency of cervical screening continued to be every three years from age 25 to age 49, but changed to be every five years for women from age 50 to 64 plus 364 days of age. Women on non-routine screening were invited up to age 70 years plus 364 days of age. Women under the age of 25 who had already been invited for a test as part of the screening programme continue to be invited for screening, regardless of whether her recall date was before or after she had reached 25 years and regardless of whether she had attended for screening or not.

- Cervical cytology was the primary screening test until March 2020, when HPV testing was introduced as the primary screening test. All women are now screened every 5 years.
- In 2018/19, 407,854 cervical screening tests were processed. The uptake rate for cervical screening was 73.1% with 1,030,703 eligible women having participated in the screening period as at 31st March 2019. In 2017 there were 276 invasive cervical cancers diagnosed annually (screened, symptomatic and incidental cases). <https://www.isdscotland.org/Health-Topics/Cancer/Cancer-Statistics/Female-Genital-Organ/#cervix>

Governance

- National Services Division (NSD) provides national co-ordination for the Scottish Cervical Screening Programme. There are 14 territorial NHS Boards who are responsible and accountable for the delivery of a high quality, safe and effective cervical screening service to its resident eligible population. Laboratory services were provided by nine cytology laboratories until 2014, now all HPV testing and cytology are carried out in two laboratories which are now centrally commissioned via NSD. There is also a nationally commissioned Scottish Cytology Training School. Since the implementation of HPV primary testing, cytology EQA is being sought from England.
- The UK National Screening Committee advises Ministers and the NHS in the four UK countries about all aspects of screening policy. The Scottish Screening Committee holds responsibility for advising Scottish Government and Ministers, providing strategic direction to NHS Scotland. The Scottish Screening Review 2018 recommended the establishment of a new National Screening Oversight Function to provide oversight, at a national level, of all parts of the screening pathway. This Function is currently being established and will be accountable to Board Chief Executives and the Scottish Screening Committee. Board Chief Executives delegate their Accountable Officer role locally to the Director of Public Health. This is further delegated to the Board Screening Coordinators who are usually a consultant or specialist in public health with a remit to oversee the delivery, quality and effectiveness of the screening programme for the resident eligible population. External quality assurance of screening programmes is delivered by Healthcare Improvement Scotland. National Services Division coordinates the internal Quality Assurance and Governance structure for the programme, where there is an overarching Programme Board.

The National Invasive Cervical Cancer Audit and Duty of Candour

- The National Invasive Cervical Cancer Audit dataset was developed due to an inability of NHS Health Boards and the Scottish Cervical Screening Programme to produce benchmarked, comprehensive data about the circumstances relating to the development of invasive cervical cancer despite the presence of a screening programme. There was previously an audit proforma in place for NHS Health Boards to record invasive cancer audit data. This proforma was developed by the Screening Co-ordinators and laboratory service and was limited in extent, with no information gathered on the process of calling and recalling participants, the accuracy of the histological and colposcopic confirmation of a screen-detected abnormality, or of the treatment. This proforma was neither consistently used nor comprehensive enough for the current screening programme, nor was the data collated at a national level. Thus, many aspects of the programme, essential for the successful prevention of invasive cervical cancer, were not subject to systematic evaluation.
- The new dataset developed in 2014 for national adoption in 2015 allows scrutiny of the full patient pathway and processes of cervical screening and their effectiveness. The dataset allows audits that will lead to better detection, diagnosis and treatment of cervical cancer. One purpose of the audit is to allow a better understanding of the reasons for false negative results and to promote learning and service improvement. While developing the dataset it was not anticipated that audits of participants' tests would be passed on to the participant should the audit identify that they might have been managed differently. It was developed to contribute to continuous quality improvement, education and training.

Ex. A-10

- The cases subject to the audit are submitted to Public Health Scotland to allow for national analysis and Public Health Scotland provide information from Cancer Registry to NHS Boards to ensure that all cases are included. This provides a cross-check with NHS Board-based systems in laboratories, gynaecology and oncology services.
- The outcome of the national audit is shared with the relevant programme governance groups and the NHS Board Screening Coordinators. The learning from local NHS Board outcome data has also been shared with other NHS Boards.
- Patient information leaflets indicate that data will be used for audit, research, education and service improvement. There is not a consent form for participation in screening or an opt out option for audit. Attendance for screening is deemed implied consent.
- Duty of Candour on health, care and social work services came into effect on 1 April 2018. The overall purpose of the duty is to ensure that organisations are open, honest and supportive when there is an unexpected or unintended incident resulting in death or harm. All NHS Boards should be following the Duty of Candour Procedure (Scotland) Regulations 2018. There is not however any national guidance on how the regulations should be applied for screening.
- Since April 2018 NHS Boards have a duty to be contacting participants if the result of the audit suggests their management should have been different. Discrepancies in management are recorded and an assessment made as to whether management was reasonable.
- The patients' clinical information is kept by the service provider. The multidisciplinary team in each Health Board reviews the outcome of each audit and the pathology, clinical stage and prognosis of each patient. If it is felt that the audit results would have resulted in a change of management, the team then considers two major factors in deciding whether or not there was a serious adverse event: was the change in cytology (or any other clinical element) within the normal range of screening performance? And was the impact on the patient considered moderately harmful? For example, a patient diagnosed and treated with a FIGO Stage 1A cancer which was locally excised would not have suffered moderate harm, her prognosis is excellent. If, however, there was a serious error outside of normal practice standards and moderate harm for the patient e.g. FIGO Stage 1B or worse, the multidisciplinary team should ensure the patient is written to and asked if they would like a meeting to hear the results. There are no programme specific guidelines on when to disclose information to a patient, instead, the approach is by consensus.
- All screening programmes have a generic adverse event policy. Cytology is not specifically mentioned. The National Screening Programme does not keep data on how many women are notified or attend for a meeting. Numbers are believed to be very small. There do not appear to have been any legal cases documented by the Central Legal office for Clinical Negligence and Risk in the last 10 years. The programme encourages disclosure and thinks it mitigates risk and addresses the patient's need to know. Auditing cytology in Scotland is influenced by their use of automated scanning of slides. All reviewed slides which were originally processed on the Hologic scanner are reviewed on the Hologic review scope to check for the presence of abnormal cells within the 22 fields of view. The slides are blinded during the review but the current SCCRS system precludes the option of reviewing the slides as anonymised samples within the routine workload.
- Educational meetings are held with all laboratory staff involved in cervical cytology to review the slides and outcome of the overall audit. The aim is to look for any common themes or areas of diagnostic weakness and to address these through targeted internal and external training. Any areas of concern are also shared with the training school to inform future training programmes.

The Expert Reference Group's response to the recommendations in *Cervical screening in cases of cervical cancer in Ireland between 2008 - 2018: RCOG Independent Expert Panel Review*

In December 2019, following the publication of the Royal College of Obstetricians and Gynaecologists' (RCOG's) Independent Clinical Expert Panel Review of CervicalCheck, the Minister for Health requested that the Expert Reference Groups incorporate consideration "of the Expert Panel's recommendations on interval cancer audit and disclosure in their ongoing deliberations, along with international best practice and consideration of the wider environment including any other expert input the groups deem necessary". ⁽²⁸⁾

The Expert Reference Group considered these recommendations, and its response to each of the recommendations can be found in Appendix 5b. The recommendations were helpful in our deliberations, but do not change any of the recommendations in our report.

Section Five:

Recommendations for the Management of Invasive Cancers in the Cervicalcheck Screened Population

Consent and information resources in the CervicalCheck screening programme

Currently, all patients participating in the CervicalCheck programme sign informed consent to participate in the programme. Patients are informed that cervical smears do not detect all cervical cancers. Additional information on the occurrence of interval cancers should be made available from the start of the patient's journey through screening. When participants join the screening programme, they should be informed that CervicalCheck will undertake anonymised cytology audit and will routinely review other programme processes, including colposcopy performance and pathology, for the purpose of programme quality assurance. It is essential that participants are informed that audit is integral to the screening service but that, should they later wish to withdraw consent from the screening service, they may. This process should be reiterated at each stage of the screening process. Particular attention should be paid to consent when carrying out smear tests and conducting colposcopy examinations.

Recommendation 1: Women should continue to be provided with all the information they require in order to help them make an informed choice to consent to participate in the CervicalCheck programme. Current informational materials should be revised in order to reinforce the information on the benefits and limitations of screening. These materials should continue to include explicit information on the occurrence of interval cancers. They should also include information on how women can request a review of their case, if desired. Expanded content on data-sharing arrangements between CervicalCheck and the National Cancer Registry Ireland (NCRI) should be included. The Privacy Notice provided to patients in relation to their participation in the CervicalCheck Programme may need to be updated to explain what personal data the HSE will share with the National Cancer Registry Ireland (NCRI) and any other third parties, including but not limited to the purpose(s) of processing, the legal basis for processing, etc., to ensure compliance with data protection law.

Patient-requested reviews of invasive cervical cancers

Any woman with a negative screening result who is subsequently diagnosed with an invasive cancer should have access to any information necessary in order to better understand her diagnosis. Recent commentary, including the Scoping Inquiry into the CervicalCheck Screening Programme conducted by Dr Gabriel Scally, was critical of the manner in which information was provided to women. All women must have access to a patient-requested review; this has not been previously available in the CervicalCheck programme. The Expert Reference Group did not recommend restricting reviews to women with interval cancers, as international experience has concluded that all invasive cancers should be reviewed.

There are many challenges associated with completing such reviews, including, but not limited to, protocols for classification, hindsight bias, and logistical challenges. Continually updated, evidence-based, robust standard operating procedures (SOPs) are required for conducting reviews.

We estimate that approximately 160 patients per year who participate in screening will be diagnosed with cervical cancer, the majority of whom (87%) are diagnosed because they participated in the CervicalCheck programme and would be considered a success of the programme. Approximately 30 patients per year (13% of all patients with cervical cancer) develop interval cancers and may question why this occurred. If, as experienced in the UK, more than 50% of all patients request a review, this would comprise at least 80 reviews annually. As an audit has not been undertaken for more than 2 years, there may be another 160–320 patients requesting reviews. Experience in two national health jurisdictions (that responded to the international survey) show that reviews typically take 6 to more than 12 months to conduct. The RCOG review of 1,034 Irish patients took a year and was complex to execute. We recommend initiating patient-requested reviews as soon as possible after approval of this report. Realistically, this is likely to take at least 6 months to begin.

Recommendation 2: CervicalCheck should establish a process to conduct patient-requested reviews of all invasive cancers (both interval and screen-detected cancers) and establish a standard operating procedure (SOP) for this purpose. Patient-requested reviews should only be undertaken following receipt of written consent from the patient. These reviews should be available to all women diagnosed with invasive cancers, including historic cases of women who did not participate in any other National Screening Service or Royal College of Obstetricians and Gynaecologists cytology review processes. Based on international experience, CervicalCheck should advise that a patient-requested review may take more than 12 months to complete.

Recommendation 3: The findings of all patient-requested reviews should be fully disclosed, and arrangements for this will be included in the CervicalCheck SOP. It is further recommended that the responsibility for disclosure of the review outcome rests with the treating clinician, generally the colposcopist or oncologist. This disclosure will be conducted in collaboration with the CervicalCheck programme and the woman's general practitioner (GP). CervicalCheck must notify the disclosing clinician of the outcome of the review, and in turn, the disclosing clinician must confirm with CervicalCheck that disclosure has taken place. Discordance in cytology review is not unexpected or unanticipated. This would not meet the definition of a patient safety incident. If a serious adverse event is identified, HSE policies must be followed.

Programmatic review of cytology

The Expert Reference Group's international survey found that 11 of the 17 programme respondents conduct audits of invasive cancers. All reported audits involved cytology review, a minority of which were blinded. Programmatic review of cytology is standard practice internationally for quality assurance and for professional education purposes.

The majority of international programmes regard interval cancers as expected and unavoidable. Clinical audits which are not blinded introduce retrospective bias and will detect changes in a significant percentage of previously negative cytology in women diagnosed with invasive cervical cancer (30–55%). Most jurisdictions do not consider these audit findings to constitute adverse events.

Recommendation 4: The Expert Reference Group recognises the educational value of programmatic review of cytology of all invasive cancers including interval cancers. The Expert Reference Group therefore recommends that Clinical Audits be conducted only where either (1) such Clinical Audits are both blinded and anonymised; or (2) legislation protecting the confidentiality of Clinical Audits is passed by the Oireachtas. If such Clinical Audits are conducted, CervicalCheck will include the outcomes of such Clinical Audits in an annual report. The results of the Clinical Audits will be anonymised and/or confidential under future legislation, and therefore results of the Clinical Audits cannot and will not be disclosed in respect of individual cases reviewed.

Interval cancer rate

While interval cancer rates are an established KPI for breast cancer screening, the measure is not routinely calculated for cervical screening. Six respondents to the international survey calculate and report interval cancer rates internally. However, a calculation methodology has not been agreed; hence, international benchmarks have not yet been determined. SOPs are in place between the BreastCheck programme and the NCRI to calculate the interval cancer rate for BreastCheck; CervicalCheck should develop similar processes.

Recommendation 5: The CervicalCheck programme should develop a new KPI, the interval cancer rate. The programme should liaise with other international screening programmes and the International Agency for Research on Cancer (IARC), specifically with regard to:

- Definition of interval cancers
- Methodology to calculate the interval cancer rate, and
- Benchmarking for participating programmes.

Recommendation 6: Implementation of the recommendations of the Scally Report should ensure that communication with NCRI is strengthened to enable a more timely validation of invasive cervical cancers. This includes consideration of the development of a population screening registry or equivalent in collaboration with the NCRI. Implementation of the individual health identifier would facilitate this process.

Open disclosure practice

The *Scoping Inquiry into the CervicalCheck Screening Programme*, by Dr Gabriel Scally, has recommended that the “National Screening Service should consider, with external assistance, the relevance of the HSE policy on ‘Open Disclosure’ as it develops in light of this Scoping Inquiry, for all of its screening programmes”. The review of invasive cancers represents an opportunity for the discussion and disclosure of findings and the identification of any potential limitations of previous CervicalCheck screenings. The Expert Reference Group has therefore considered the requirements for open disclosure.

In 2013, the HSE implemented the Open Disclosure Policy across all healthcare sectors. The most recent version of this policy defines open disclosure as “an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to ongoing care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident”.⁽⁸⁾

The HSE National Quality Improvement team made an interim revision to the HSE Open Disclosure Policy on 12 June 2019, which replaced the HSE Open Disclosure Policy dated 8 October 2013.⁽⁹⁾ The interim policy states that it “will be subject to further review following: (i) the development and publication of operational guidance for clinical audit of interval cancers in screening services by the Expert Working Group on the Clinical Audit of Interval Cancer in the CervicalCheck Screened Population. This guidance will set out the principles and processes for how audit and individual case review should be undertaken following a diagnosis of interval cancer in the screened population and (ii) the commencement of provisions for mandatory open disclosure in the forthcoming Patient Safety Bill”.⁽⁹⁾

Historic failings pertaining to the management of disclosure in the CervicalCheck programme have been well documented.⁽⁷⁾

The Expert Reference Group acknowledges that disclosure has taken place following the audit of interval cancers within the CervicalCheck programme and as part of the review undertaken by the RCOG.

The Expert Reference Group has recommended the development of an SOP for patient-requested reviews of interval cancers. CervicalCheck should disclose the findings of patient-requested case reviews of interval cancers. This should be reflected in future CervicalCheck quality assurance guidance and monitoring systems.

CervicalCheck quality assurance documentation should be amended and KPIs developed to validate and monitor interval cancer reviews and the implementation of disclosure.

In circumstances where CervicalCheck is meeting the relevant KPIs and operating to the required standard, interval cancers, including false negative cancers, should not be considered patient safety incidents as defined by the current HSE Open Disclosure Policy. However, the findings of all patient-requested individual case reviews should be disclosed, as will be set out in the interim CervicalCheck SOP which is in development

Implementation of disclosure for patient-requested reviews of interval cancers is resource intensive and will need to be appropriately supported.

Recommendation 7: The HSE should continue to build and promote understanding, confidence and trust in CervicalCheck and other screening programmes through public information, engagement and education for participants, clinicians, and the wider society. Women should be made aware that they may, separately from any review process, request access to their screening records at any time.

Resources for future clinical audit

Recommendation 8: The Expert Reference Group recommends that the necessary resources should be provided to CervicalCheck in order to implement these recommendations. An implementation team should be established in order to ensure continued implementation of disclosure according to the outlined recommendations. Processes should be continually monitored in the context of updates to the Patient Safety Bill 2018, the General Data Protection Regulation (GDPR), tort reform and emerging international practice.

Implementation planning and operational guidance for clinical audit for invasive cervical cancers

Implementation of recommendations

The Expert Reference Group recognises that the recommendations in this report present significant planning and operational challenges for the CervicalCheck Programme. We appreciate that the first priority for CervicalCheck is to roll out the new approach to screening, Primary HPV testing, in 2020, as well as reopening the programme after the service interruption resulting from the Covid-19 pandemic. Primary HPV testing will be a more sensitive predictor for women at high risk of precancerous changes in the cervix and, when accompanied by reflex (concomitant) cytology, should improve the detection rate and treatment of high grade dysplasia.

An Implementation Planning Committee is being established to develop the methodologies and standard operating procedures for these recommendations.

Additional challenges to successful implementation must be understood:

In 2020, concerns have arisen related to the growth in legal cases arising from participation in the programme. Prior to May 2018, the State Claims Agency was notified of 10 cases. Since then, by June 2020, there are 185 active claims not yet concluded. Additionally, the Royal College of Obstetricians and Gynaecologists (UK) review (published December 2019) of cytology in 1034 women with cancer has already generated 83 formal requests to CervicalCheck for patient data, which may then lead to more claims. Furthermore, the Supreme Court Ruling of “Absolute Confidence” in the Morrissey case will inadvertently create the erroneous impression that all cytology must be 100% accurate. This is unachievable; the reality, internationally, is that in women diagnosed with cancer, cytology reports will change in 30 to 55 % of cases when audited in unblinded reviews. Based on limited information in the small number of cases concluded and the unknown number of future cases which might generate a financial settlement, the liability to the State could be in the range to tens of millions to hundreds of millions of Euros. Since the 2019 operating budget of CervicalCheck was €34 million, such liability would render the programme unsustainable. The other key element to consider is the impact on staff, particularly pathologists, cytotechnologists and gynaecologists, who might have to devote days or even weeks to each court case many times in each year, undermining time available for screening and damaging recruitment and retention in services which are already under strain as a result of staff shortages. Ireland is unique internationally in regard to the litigation environment and the potential for harm to its current and future screening programmes.

The aim of this report is to support Ireland’s excellent CervicalCheck programme in order to provide quality-assured, well organised, freely accessible public screening to current and future participants in order to reduce incidence and mortality from cancer. The balance between respect for the patients’ need to know their information in an open and supportive health care environment versus the duty to future participants and staff to maintain a viable programme has weighed heavily on our approach to implementation.

Patient-Requested Reviews

The HSE and the National Screening Service must engage with and inform the public, patients, politicians and media of the benefits and limitations of screening programmes. It is vital that screening participants appreciate that tests will substantially reduce their risk of developing cancer, but cannot prevent or diagnose all cancers and that interval cancers will arise in any population screening programme. A comprehensive communications plan must be developed and implemented prior to the roll out of Patient-Requested Reviews. The Expert Reference Group recognised that the conduct of Patient-Requested Reviews could influence legal claims which may potentially compromise retention of professional staff and costs of providing the Programme. The HSE, Department of Health and Government must consider putting safeguards in place to ensure sustainability of screening. A legal framework for screening needs to be explored.

The Implementation Planning Committee will develop the operational guidance and Standard Operating Procedures including patient information and consent, review of screening experience, blinded audit of cytology and cooperation between CervicalCheck, colposcopy units and treating clinicians in providing full disclosure.

Programmatic Audit of Cytology

The introduction of primary HPV screening this year will reduce cytology volume by 85%. Cytology will only be carried out in women testing positive for HPV. These women comprise a higher risk population than all well women who previously were screened by cytology alone. Cytotechnologists will inevitably identify a higher number of abnormal cells in this population and will direct more women to colposcopy. The skills and expertise required differs from routine screening. Programmatic audit should be introduced prospectively for cytology arising in the primary HPV screened population. The Quality Assurance and professional education will be aligned with the new screening methodology.

The Implementation Planning Committee will develop the Standard Operating Procedures for an anonymised and blinded review process. The audit processes will commence once resources (staff and funds) are available and the screening programme has resumed full operation.

Development of an Annual Interval Cancer Rate

This new Key Performance Indicator for CervicalCheck will be an additional programmatic audit measure, similar to BreastCheck.

The parameters defining an annual Interval Cancer Rate must be agreed with other international screening programmes (and IARC), where a few have already begun this work. A standard rate (or range) must be developed.

Data capture from the National Cancer Registry of Ireland must be developed and implemented and be compliant with data protection regulations. A Memorandum of Understanding has already been agreed between the National Cancer Registry of Ireland and the National Screening Service.

The Implementation Planning Committee can commence this project immediately, building on the current links between the National Cancer Registry of Ireland and NSS.

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Appendices: Appendix 1

Terms of Reference

Clinical Audit of Interval Cancer in the Screened Population

TERMS OF REFERENCE

11 September 2019

Background

Population screening is a public health tool designed to reduce population mortality and/ or morbidity by early detection. Each screening test is therefore aimed at identifying people who are asymptomatic but who are at higher risk of having or developing the condition screened. All programmes aim to maximise the benefits of early detection while minimising potential harms. Screening tests are not perfect and while such programmes have contributed to a significant reduction in deaths and disease morbidity, not all people diagnosed with the disease will have been detected by screening. Given the limitations of screening, false negative and false positive cases are unfortunately an inevitable and expected outcome. There are international and national guidelines describing anticipated false negative and false positive rates in a screening programme that is working even to the highest standards.

A cancer diagnosed in the period of time after a negative screening test and before the next screening episode is referred to as an interval cancer. Interval cancers are an inevitable, anticipated and unavoidable component of every screening programme. Indeed, there are published reports and guidelines detailing the expected rate of interval cancers in a population screening programme.

Quality Assurance (QA) is a central component of population based screening programmes. A robust QA programme ensures that each programme is functioning to a satisfactory level. All quality measurements are bench marked, collated and complied with National and International standards. The monitoring of the rate of interval cancer is one of many programme performance indicators which together allow those delivering the programme to reassure health authorities and patients about the quality of the service offered.

Audit and feedback are used in all health care settings, involving all health professionals, either as individual professions or in multi-professional teams. Clinical audit is an essential element in quality improvement and patient safety.

In Ireland, the three cancer screening programmes have different timelines and technologies.

This review will identify the key principles and processes upon which the future practice of audit of interval cancers will be based.

Purpose

To define the future audit processes and review guidance for interval cancers in the National Screening Service based on international evidence and best practice.

Objectives

Having regard to the findings of the Scally Review, international best practice and any other evidence deemed appropriate, the Expert Reference Group (ERG) is asked to

1. Establish the current audit practices of the three cancer screening programmes and compare to international best practice.
2. Establish any review practices, in relation to interval cancers, of the three cancer screening programmes, and compare to international best practice.
3. Determine best internationally accepted practice for addressing interval cancers.
4. Develop, in line with National Standards for Clinical Practice Guidance Development, operational guidance which sets out the principles and processes for how audit of interval cancers should be undertaken following a diagnosis of interval cancer in the screened population. This guideline should:
 - 4.1 Review standardised informed consent processes
 - 4.2 Outline the potential role of audit in such situations in Ireland, such that cancer screening programmes may be assessed with regard to their operation within agreed standards. This will take into account feasibility, safety, practicality, cost-effectiveness, legality and risk. Appraise the various options available and outline the future method of clinical audit and review in Ireland.
 - 4.3 Outline the future methodology for individual case review in such situations in Ireland including any data protection requirements.
 - 4.4 Establish a process for open disclosure and communication as it pertains to both interval cancer audit and to individual case review for a service user. This will take into account the HSE open disclosure policy, legislative requirements and best practice guidelines. This will also take account of patient's needs, ethical responsibilities, the impact on healthcare professionals and programme sustainability.
5. Outline the benefits and challenges for the National Cancer Screening Programmes regarding implementation of the proposed systems of audit of interval cancer.
6. Recommend the commencement date for the newly proposed system of audit of interval cancer.

Patient Engagement

The Expert Groups will ensure that there is patient engagement as a key input to the design of the new audit and review process. The Expert Groups will include two patients and / or public representatives. In addition, the design process will include consultation with the relevant Public & Patient Involvement (PPI) forums and research will be undertaken on the approach to the audit and review process in other EU countries, which will also indicate the approach taken with the public and patients.

Scope

The Screening Programmes covered by the clinical audit of interval cancers will be:

- CervicalCheck (the National Cervical Cancer Screening Programme)
- BreastCheck (the National Breast Cancer Screening Programme)
- BowelScreen (the National Colorectal Cancer Screening Programme)

Deliverables

A document for each of the three cancer screening programmes will be developed and will detail recommended processes based on agreed principles and guided by best practice.

These three documents will form part of an overarching operational policy document for cancer screening.

Governance

There will be an overarching Steering Group with two Expert Reference Groups. The Steering Group will comprise the two commissioners and the two Expert Reference Group chairs. There will be a shared project secretariat to ensure alignment between the two Expert Reference Groups.

The two Expert Reference Groups will be:

- Cervical and Bowel Screening
- Breast Screening

There will be three working groups which will support each respective screening programme.

The Steering Group will bring the report to the HSE Leadership Team for final approval.

Membership

The Project Steering Group has oversight of the entire project. The steering group will agree principles and approve recommendations from the Expert Reference Groups. It will comprise the two HSE review commissioners and the two chairpersons, supported by the Office of the Chief Clinical Officer.

All screening programmes will adhere to overarching principles. The expert group membership will comprise of:

- External Chairperson
- Patient Advocates
- Patient Representatives
- Screening Clinicians
- International Screening Experts
- Academic and research expertise
- National Clinical Programme leads
- Clinical Audit expertise
- Public Health

Project Secretariat

A project secretariat will be formed with a project manager appointed and support provided by the NSS Programme Evaluation Unit (PEU), Library services, Legal Services, Public Health and the National Cancer Control Programme.

Project Process

The project will be approached in four stages:

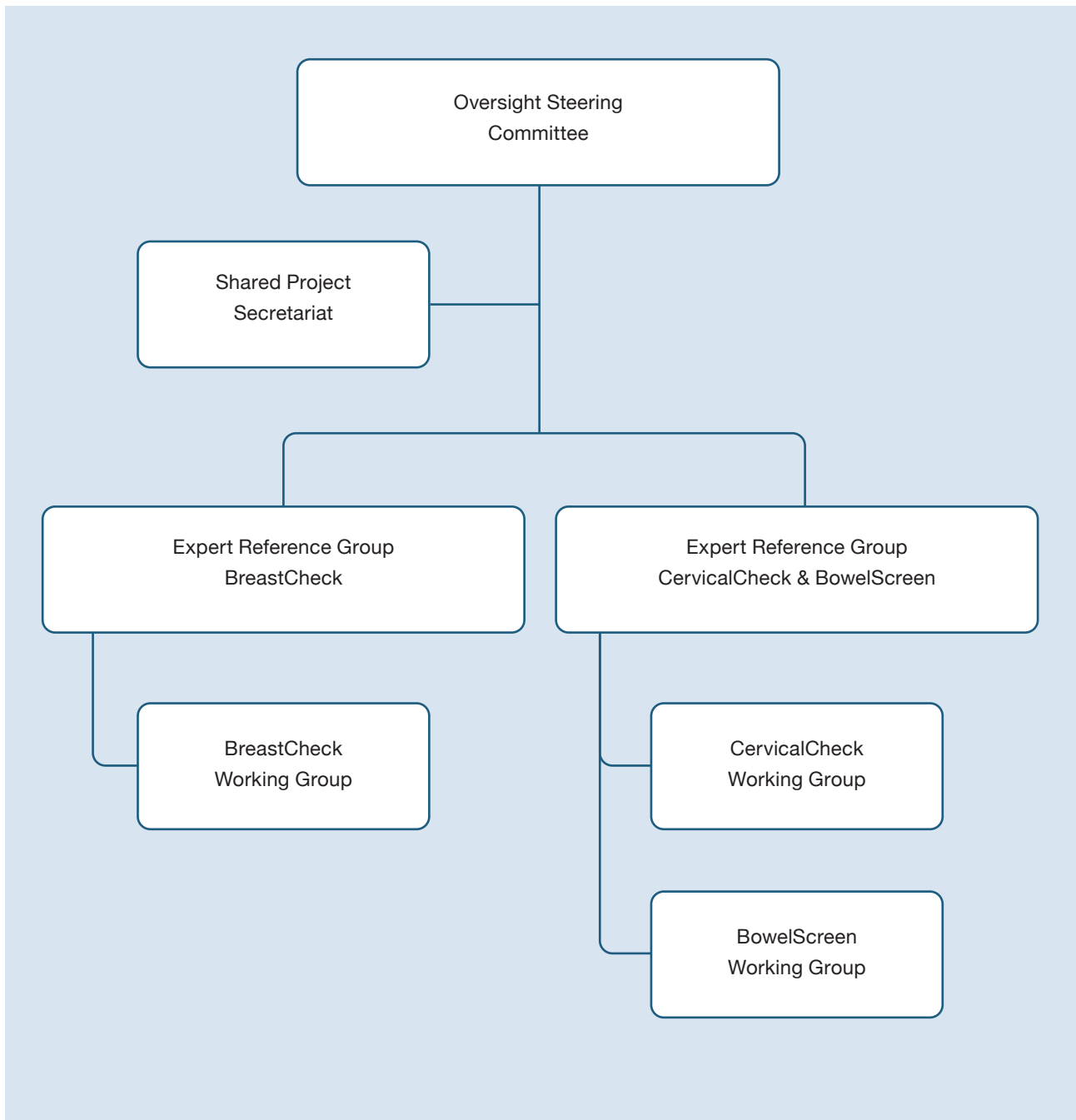
- Stage 1: An international literature search and communications with other international and regional cancer screening programmes
- Stage 2: Development and design of the draft audit cycle, tools and methodologies
- Stage 3: Consultation with key stakeholders (i.e. Patient Representatives, HIQA, DoH, SCA) re draft proposals
- Stage 4: Review and final report

Timeframe

To report within four-six months from its first meeting.

Ex. A-10

Clinical Audit of Interval Cancer in the Screened Population



Clinical Audit of Interval Cancer in the Screened Population

Members List

Project Oversight Steering Group

Project Commissioner - Chief Clinical Officer, HSE	Dr Colm Henry
Project Commissioner - National Screening Service, National Director	Damien McCallion
Chair - CervicalCheck & BowelScreen Expert Reference Group	Professor Susan O'Reilly
Chair - BreastCheck Expert Reference Group	Professor Risteárd Ó Laoide
Lead Project Report Writer / Professor of Public Health, UCC	Professor Orla Healy
Chief Clinical Office, General Manager	Deirdre McNamara

CervicalCheck & BowelScreen Expert Reference Group

Chair	Professor Susan O'Reilly
Clinical Director CervicalCheck, NSS/CervicalCheck Working Group Co-Chair	Dr Lorraine Doherty
National Clinical Director, National Women and Infants Health Programme/CervicalCheck Working Group Co-Chair	Dr Peter McKenna
Interim Clinical Director BowelScreen / BowelScreen Working Group – Co Chair	Professor Pádraic MacMathuna
Professor of Public Health, UCC/BowelScreen Working Group – Co Chair	Professor Orla Healy
National Cancer Registry Ireland, Director	Professor Kerri Clough
Director of Public Health, NSS	Dr Caroline Mason Mohan
National Cancer Control Programme, National Director	Dr Jerome Coffey
Consultant Epidemiologist/Director of Evaluation, NSS	Professor Patricia Fitzpatrick*
National Office of Clinical Audit	Professor Conor O'Keane
Associate Professor of Healthcare Ethics, RCSI	Professor David Smith
BreastCheck Nurse Specialist, NSS	Ruth Conboy
International External Expert on Screening	Dr Ameli Trope
Public and Patient Representative	Marie Meaney
Public and Patient Representative	Bridget Doherty
Public and Patient Representative	Niall Coffey

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence

NSS: National Screening Service; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

BreastCheck Expert Reference Group

Chair	Professor Risteárd Ó Laoide
Lead Clinical Director BreastCheck outgoing / Consultant Radiologist, NSS	Professor Ann O'Doherty
Lead Clinical Director BreastCheck incoming / Consultant Radiologist, NSS	Professor Fidelma Flanagan
Consultant Surgeon, BreastCheck, NSS	Mr Martin O'Sullivan
Head of School of Medicine / Professor of Surgery, RCSI	Professor Arnold Hill
Director, National Cancer Control Programme	Dr Jerome Coffey
Public Health, National Cancer Control Programme	Dr Deirdre Murray
Consultant Epidemiologist / Director of Programme Evaluation Unit (PEU), NSS	Professor Patricia Fitzpatrick*
Director of Public Health, NSS	Dr Caroline Mason Mohan
National Office of Clinical Audit	Professor Conor O'Keane
Associate Professor of Healthcare Ethics, RCSI	Professor David Smith
National Cancer Registry Ireland, Director	Professor Kerri Clough
Head of Services and Advocacy, Irish Cancer Society	Donal Buggy
General Practice MD	Dr David Hanlon
Psychologist	Dr Marie Ward
Dean, Faculty of Radiology, RCSI	Dr Niall Sheehy
Faculty of Radiology Representative	Dr Patricia Cunningham
Health Economist, UCC	Dr Brian Turner
International External Expert on Screening	Solveig Hofvind (Norway)
International External Expert on Screening	Kristina Lang (Switzerland)
Patient and Public Representative	Clara Clark
Public and Patient Representative	Eileen Woods
Public and Patient Representative	Brigid Doherty
Lead Project Report Writer / Professor of Public Health, UCC	Professor Orla Healy

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence

HSE: Health Service Executive; NSS: National Screening Service; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

CervicalCheck Working Group

CervicalCheck Clinical Director (Co-Chair)	Dr Lorraine Doherty
National Clinical Director, National Women and Infants Health Programme (Co-Chair)	Dr Peter McKenna
Gynaecologist/Colposcopy Consultant	Dr Francois Gardeil
Gynaecologist/Colposcopy Consultant	Dr Gunther Von Bunau
Gynaecological Oncologist Consultant	Professor Donal Brennan
General Practice MD	Dr David Hanlon
CervicalCheck Laboratory Coordinator, NSS	Maeve Waldron
Nurse Colposcopist	Anne Redmond
CervicalCheck National Laboratory Quality Assurance Lead, NSS	Dr Dave Nuttall
Medical Virologist, Director, National Virus Reference Laboratory	Dr Cillian F. De Gascun
Head of Programme Evaluation Unit, NSS	Dr Therese Mooney
CervicalCheck Programme Manager	Gráinne Gleeson
Primary Care Representative	Anne Marie Ellwood
Patient and Public Representative	Sheera Harmon
Patient and Public Representative	Maira Dillon
CervicalCheck Report Writer	James McGrath
Lead Project Report Writer	Professor Orla Healy

BowelScreen Working Group

Interim Clinical Director BowelScreen / BowelScreen Working Group Co Chair	Professor Padraic MacMathuna
BowelScreen Working Group Co Chair / Professor in Public Health, UCC	Professor Orla Healy
Colorectal Surgeon	Professor Des Winter
Consultant Gastroenterologist, UHG	Dr Eoin Slattery
ANP / CNM Nurse Endoscopist	Ann Cooney
BowelScreen Programme Manager, NSS	Hilary Coffey
Public and Patient Representative	Tom O'Keefe
Public and Patient Representative	Celia Hogan

UCC: University College Cork. UHG: University Hospitals Galway. NSS: National Screening Service

BreastCheck Working Group

Chair	Professor Risteárd Ó Laoide
Lead Clinical Director BreastCheck incoming / Consultant Radiologist, NSS	Professor Fidelma Flanagan
Lead Clinical Director BreastCheck outgoing / Consultant Radiologist, NSS	Professor Ann O'Doherty
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Clinical Director, BreastCheck Southern Unit, / Lead Consultant Radiologist, NSS	Dr Alissa Connors
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Consultant Histopathologist, NSS	Professor Cecily Quinn
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Director of Public Health, NSS	Dr Caroline Mason Mohan
BreastCheck Nurse Specialist, NSS	Ruth Conboy
Head, Programme Evaluation Unit, NSS	Dr Therese Mooney
BreastCheck Report Writer / Research Fellow RCSI	Dr Maeve Mullooly
Lead Project Report Writer / Professor of Public Health, UCC	Professor Orla Healy

* Therese Mooney, Head of PEU will attend in Professor Fitzpatrick's absence
HSE: Health Service Executive; NSS: National Screening Service; PEU: Programme Evaluation Unit; RCSI: Royal College of Surgeons in Ireland; UCC: University College Cork

Project Secretariat

Project Manager, NSS	Antoinette Morley
Executive Assistant, NSS	Administrative Team
Head of Programme Evaluation Unit, NSS	Dr Therese Mooney
Clinical Librarian	Gethin Smith
HSE Legal Advisor	Philip Lee

NSS: National Screening Service

Appendix 2: International Survey Results

Methodology

A formal survey was undertaken by the Expert Reference Group, the CervicalCheck Working Group and the Programme Evaluation Unit within the National Screening Service to gather information from international population-based cervical screening programmes on their processes for the audit and review of interval cervical cancers.

Well-established international cancer screening programmes were contacted across Europe, Canada and Australia, all of which provide comprehensive access to all eligible members of the public in jurisdictions with populations similar to or greater than Ireland's population of 4.8 million, with one exception: Northern Ireland was consulted (population 1.8 million), as it is the NHS jurisdiction geographically closest to Ireland. The survey was circulated to 22 screening programmes in May 2019. If no response was received, the contact was repeated three times. If responders required any clarification about the survey, the National Screening Service responded to all of their questions. Globally, many countries and regional jurisdictions do not have comprehensive, publicly funded cancer screening programmes, and thus were not eligible to participate.

Results

Results from an international survey on clinical audit of interval cancers in the screened population were analysed in November 2019 and are presented in this report. All comments from respondents are in *italics* and transcribed verbatim.

Seventeen countries/regions completed the survey out of 22 countries invited, giving a response rate of 77% (Figure 1). Of the seventeen countries/regions that completed the survey, eleven have an audit process in place for interval cancers. Six countries/regions do not have an audit process for interval cancers (Figure 2).

Figure 1. Flow diagram of main survey results

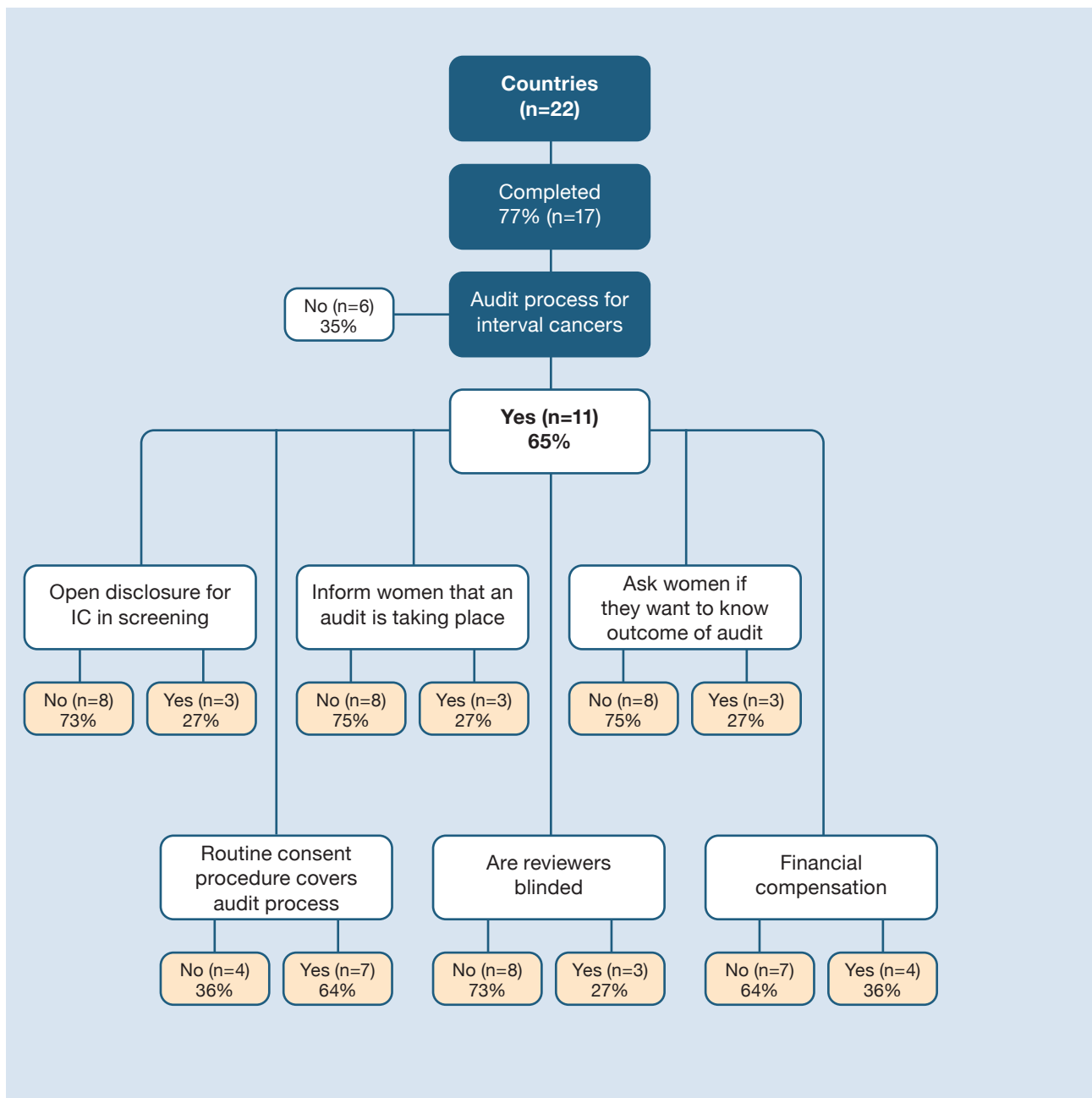
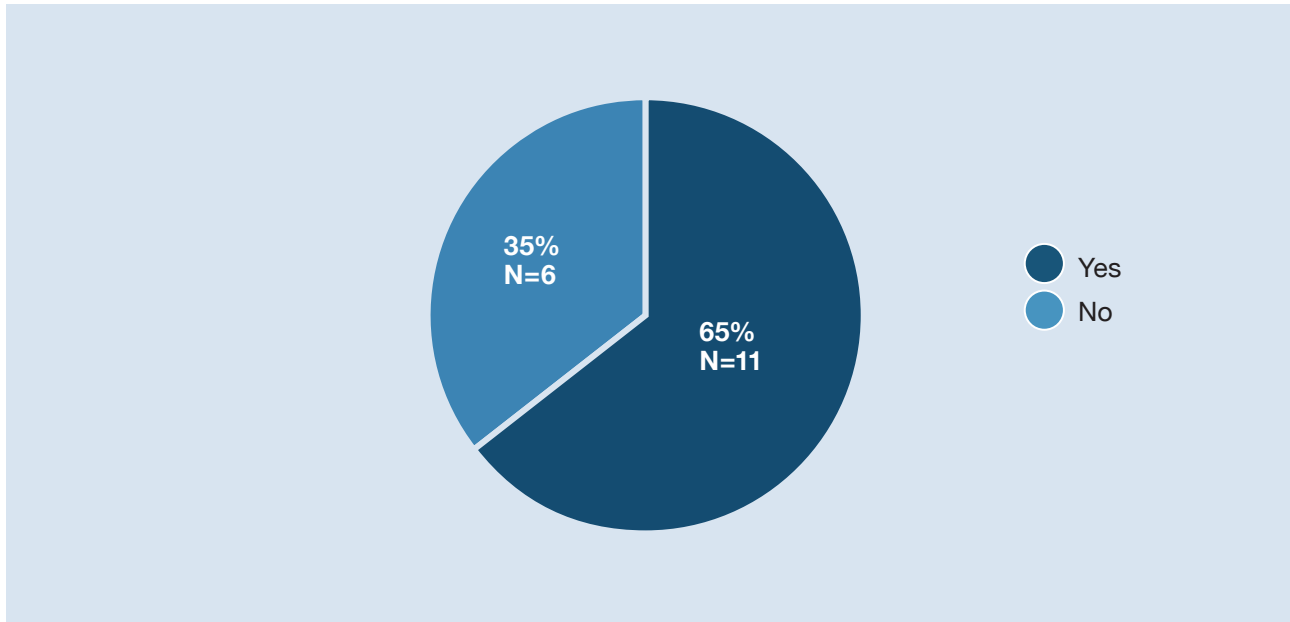


Figure 2. Does your cervical screening programme undertake an audit of invasive cervical cancers in the screened population?



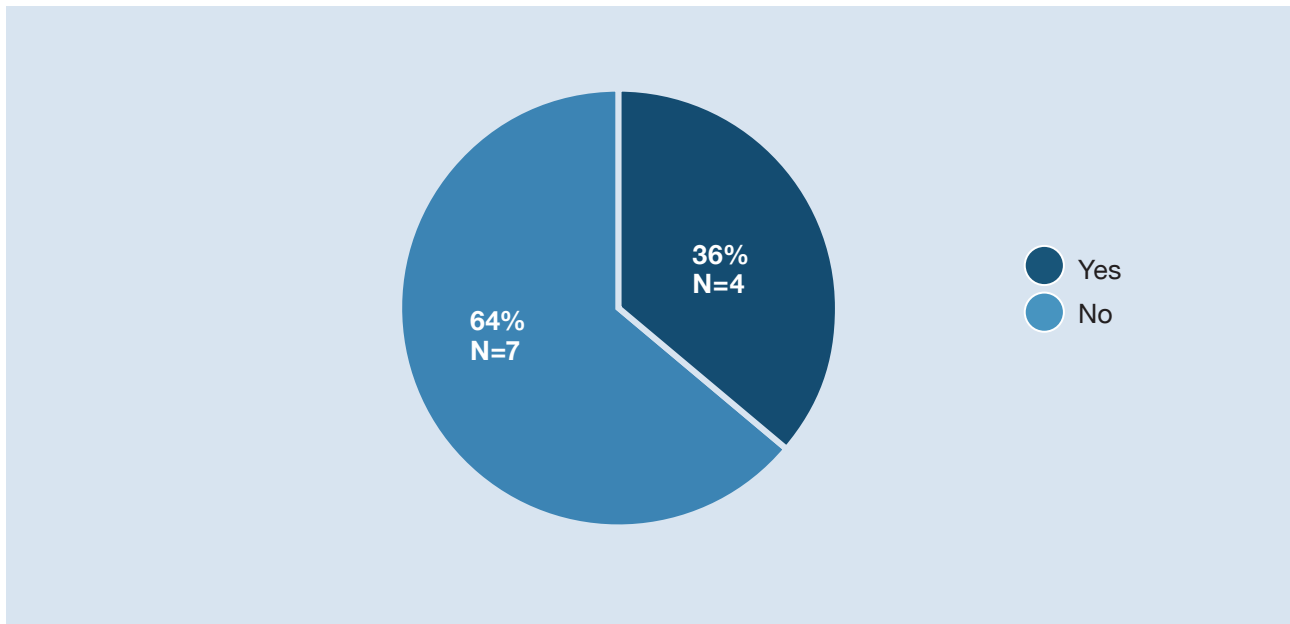
How does your cervical screening programme undertake an audit of interval cervical cancers in the screened population?

Of the eleven countries/regions that carry out audit, six countries/regions carry out routine individual patient cancer review. Three countries carry out routine programme wide review, with calculation of interval cancer detection rates. One country/region carries out a routine programme wide review, with calculation of interval cancer detection rates and routine individual patient cancer review while one country/region carries out audit at hospital level. In one country/region hospital laboratories audit all cancers and there is also a national audit process for auditing all cervical cancers.

Are control samples included with audit cases when sent for cytology review?

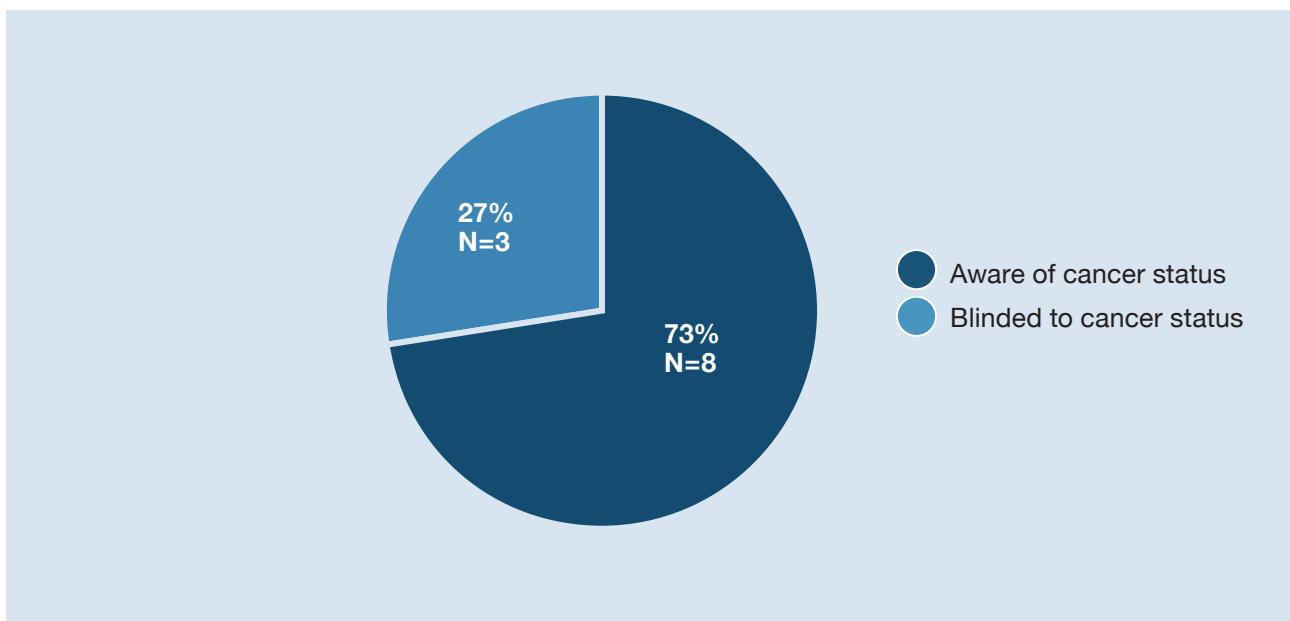
Of the eleven countries/regions that carry out audit, four include control samples with audit cases when sent for cytology review. These countries/regions were also asked how controls are selected and how many controls are included in the review. The four countries/regions answered as follows:

- 2 controls per each test. It is a control test before and after the actual test. The reviewer do know in practice which test was an audit case
- 2 controls per case, same age of women, same smear-taker and same laboratory
- We randomly assign 2 smears per each invasive interval cervical cancer case; these additional smears are chosen from the same laboratory which evaluated false negative smear
- Generally review at least 10 slides at any given audit. An equal number of known cases are included in a blinded review process where the reviewers are unaware of the outcomes

Figure 3. Are control samples included with audit cases when sent for cytology review?

When reviewing the slides of an interval cancer are the reviewers aware that the woman subsequently developed cancer, or are they blinded to this fact?

Of the eleven who carry out audit, three countries/regions carry out a blinded review.

Figure 4. When reviewing the slides of an interval cancer are the reviewers aware that the woman subsequently developed cancer, or are they blinded to this fact?

How is hindsight bias managed in interval cervical cancer reviews?

Nine countries/regions provided a response to this question as follows:

- *This is an area we are currently considering*
- *Reviewers are asked to comment on whether the original report was reasonable on any given day, with an experienced screener*
- *This review is primarily for educational purposes - it is not to estimate the rate of missed cancers*
- *Good question*
- *We are not trying to validate the entire screening programme. Our objective is to try and understand how any woman develops cervical cancer and could have this been prevented in her case*
- *I am not sure that I understand the questions. Reviewers are blinded to women's ID and cancer status, since we also use controls*
- *With difficulty but must be pragmatic and use common sense*
- *One or two pathologists review the latest screening sample. There are no checks for hindsight bias. We trust the pathologists to do their job*
- *Reviewers are evaluating all slides gained from laboratories, i.e. all false negative slides and additional slides chosen randomly (2 per each false negative one). However, specialists are aware of the objective of the review*
- *Consensus review . Not just one reviewer*
- *By blinding the reviewers to outcomes and including other cases with known outcomes (benign on follow up or high grade squamous lesions)*
- *Review of cytology is internal by hospital staff, not blinded or anonymised*

Is the interval cancer audit procedure different for cases requested for review by an individual patient versus overall programme audit?

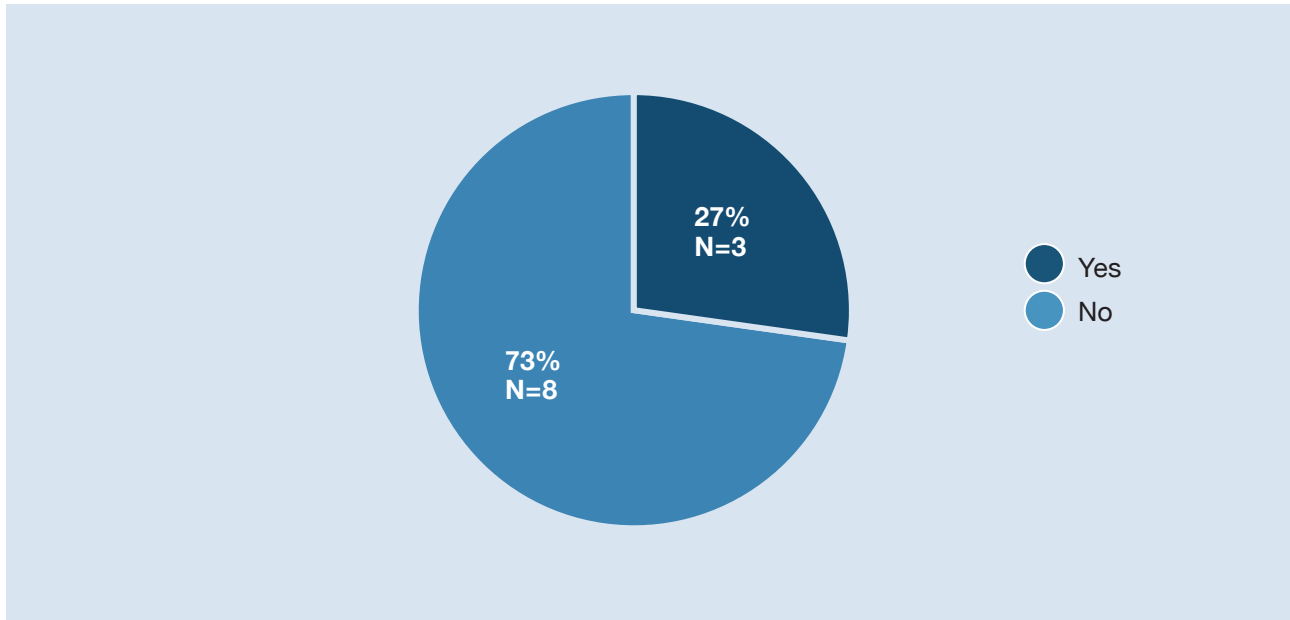
Four countries/regions answered "yes" to this question. Further information provided by those who answered yes to this question is as follows:

- *All the tests are in a programme audit but the patient can send a request to the system of patient injury compensation(NPE). Executive officers handle the case and NPE pathologist reviews the smear*
- *If a patient request the review of past smears (this is not common) before the programme audit takes place, this review is organised by patient's clinician and is usually done in the same laboratory where the smear was evaluated for the first time*
- *There is no central procedure of reviewing slides on request of a patient. A patient can only claim on court to evaluate smears once again*
- *If an individual patient or her doctor requests a review of screening tests, it is national policy to do so and to provide the results to the "caretaker" doctor, usually gynaecologist or oncologist involved, who are deemed the most appropriate to explain the findings to the patient*

Are patients informed that a cervical cancer audit is taking place?

Of the eleven countries/regions that carry out audit, three countries/regions inform patients that a cervical cancer audit is taking place.

Figure 5. Are patients informed that a cervical cancer audit is taking place?



Who contacts the women in respect of telling them that the cervical cancer audit is taking place?

Of the countries/regions that inform patients that an audit is taking place, the information provided in relation to telling women that the audit is taking place is as follows:

- *Is included in our screening information leaflets. A new specific leaflet has recently been developed for women diagnosed with cancer - to be discussed by clinician at time of diagnosis*
- *The woman should be advised by her treating clinician*
- *The colposcopist or treating doctor informs the patient*

What processes are in place to facilitate informing women that a cervical cancer audit is taking place?

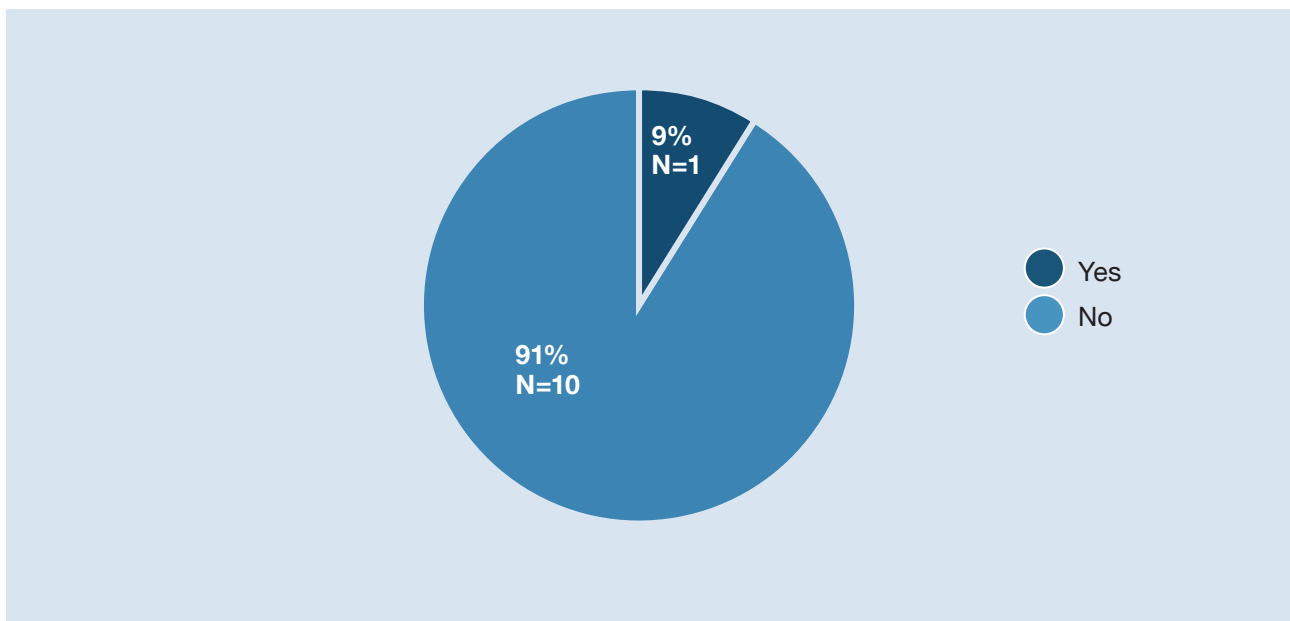
Of the countries/regions that inform women that an audit is taking place, the information provided in relation to the processes that are in place as follows:

- This process is set out in a regional framework document and trusts are currently developing local operational protocols in line with this.
- All clinicians have been advised, information on website, leaflet developed to give to women
- When a woman is diagnosed her physician should inform her that the screening programme always audits the screening that women who get cervical cancer received as a form of quality assurance and if they would like the results of that review when it is complete then they just have to ask.

Do women have a choice to be part of the audit?

Of the eleven countries/regions that carry out audit, one gives women a choice to be part of the audit.

Figure 6. Do women have a choice to be part of the audit?



What information do you give patients who are participating in an interval cancer audit?

Nine/countries regions answered this question with the following responses:

- *Women who are screened are informed of the registry and the quality assurance. They can opt out. 2 women out of 2.5 million participants have done that so far.*
- *As per leaflet issued to patient and additional FAQs if further information sought (available on our website)*
- *A leaflet called 'review of your cervical screening history'*
- *No information*
- *In general the pathologist informs the smeartaker that a test has been overseen if a ASCH or more severe smear. We are working on a standard letter that can be sent from the smeartaker.*
- *Verbal and written information*
- *Patients are not directly informed that audit is taking place*
- *Information on screening leaflet to say samples and data may be used for audit*
- *Clinician may inform patient that an audit will be done but is not required to*

How do you inform women that they will be part of an audit?

Countries/regions provided the following responses:

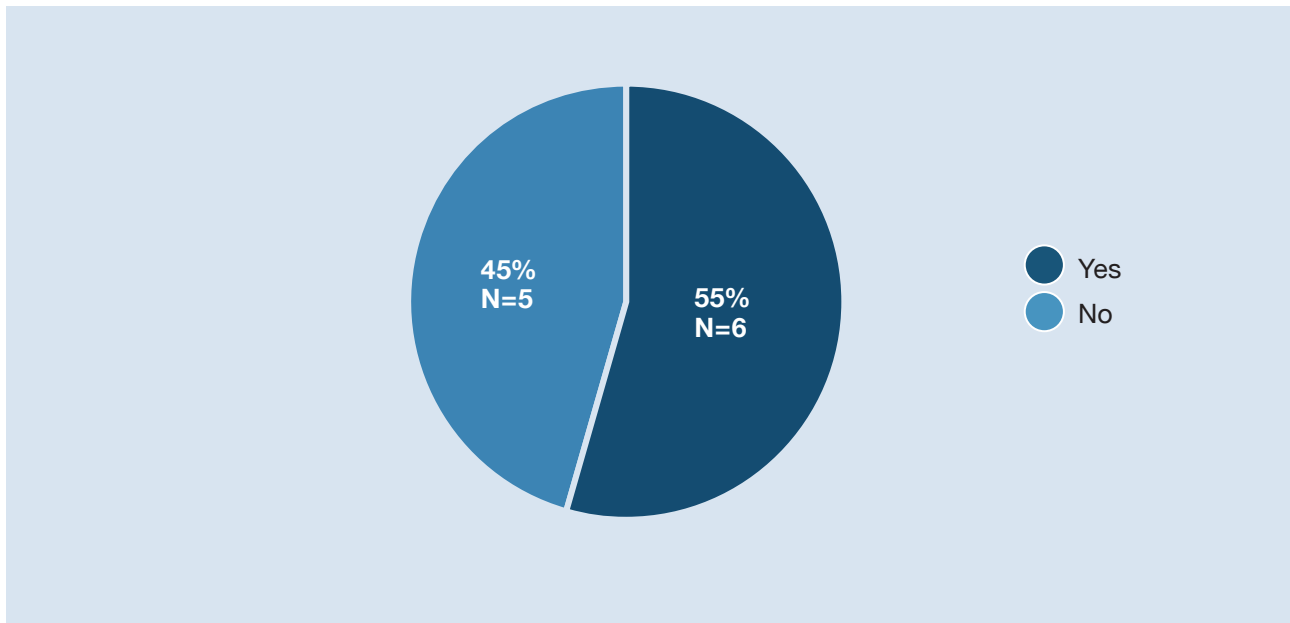
- *The screening registry and associated quality assurance is part of the invitation letter to screening that is sent to all women in the country*
- *Their clinician advises that an audit will be taking place and they can have the results*
- *They are not informed*
- *By verbal information at the time of their diagnosis*
- *Verbally*
- *Not informed unless clinician undertaking care informs them or woman asks*

In Ireland we have an open disclosure policy for medical incidents. Do you have such policy(s) in your country?

Of the eleven countries/regions that carry out audit of interval cancers, six countries/regions have an open disclosure policy for medical incidents. Of these, four countries/regions have a mandatory open disclosure policy for medical incidents in place.

Ex. A-10

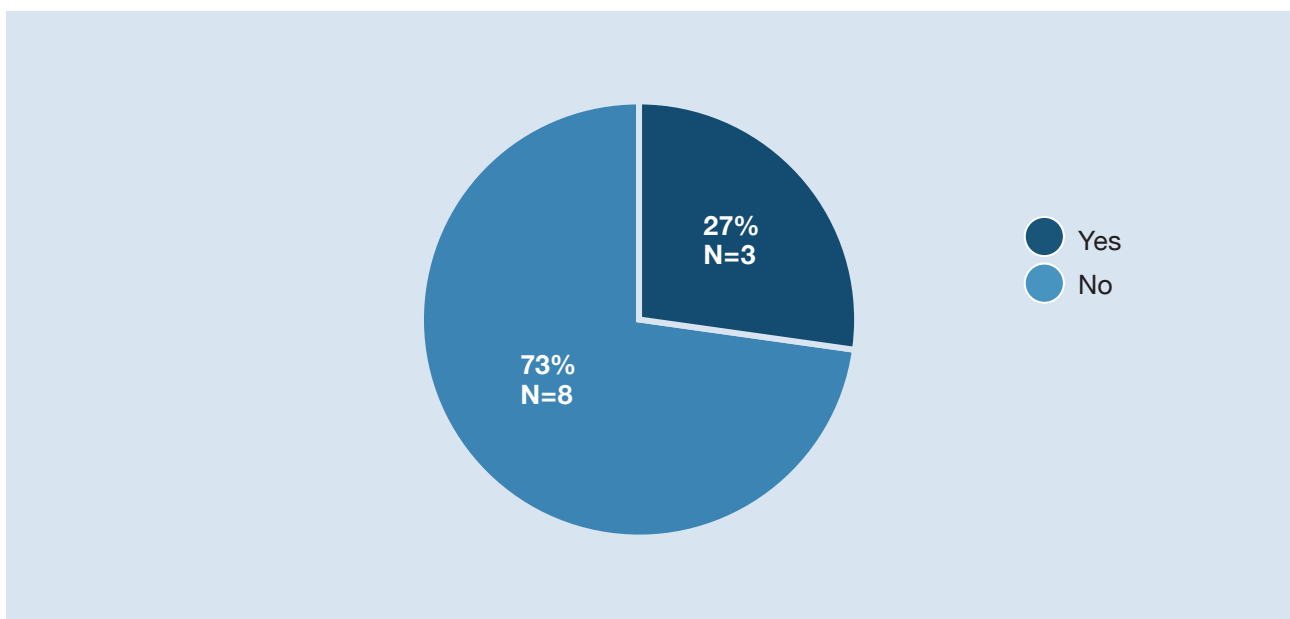
Figure 7. In Ireland we have an open disclosure policy for medical incidents. Do you have such policy(s) in your country?



Does the open disclosure / duty of candour policy extend to the results of audit of invasive interval cancers in your screening programme?

Of the six countries/regions that have an open disclosure policy for medical incidents, three countries/regions have an open disclosure policy that applies to interval cancers in screening, However one country notifies the laboratories and has no standardised protocol for communicating the results to the women and are not assured that all women receive the result.

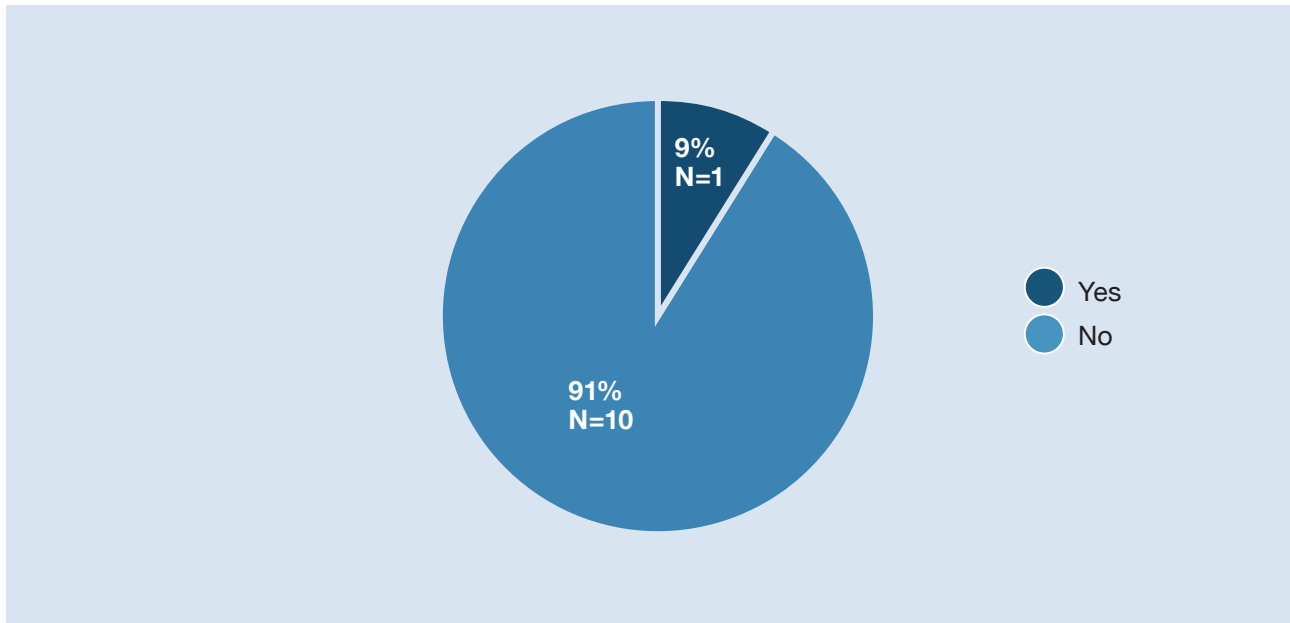
Figure 8. Does the open disclosure / duty of candour policy extend to the results of audit of invasive interval cancers in your screening programme?



Do you capture consent from clients to take part in a clinical audit?

One of the eleven countries/regions that carry out interval cancer audit one country/region captures consent from women to take part in a clinical audit. This is captured at the screening event.

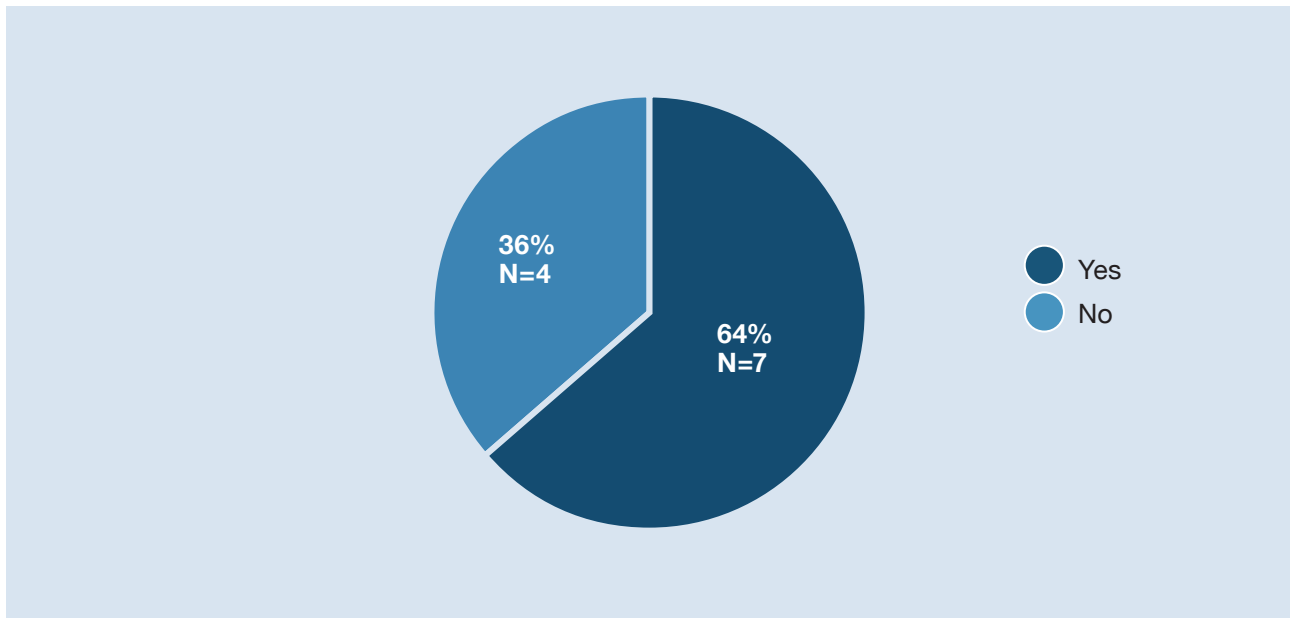
Figure 9. Do you capture consent from clients to take part in a clinical audit?



Does your routine consent procedure for screening cover the interval cancer audit process?

Seven countries/regions responded that their routine consent procedure for screening covers the interval cancer audit process.

Figure 10. Does your routine consent procedure for screening cover the interval cancer audit process?



Ex. A-10

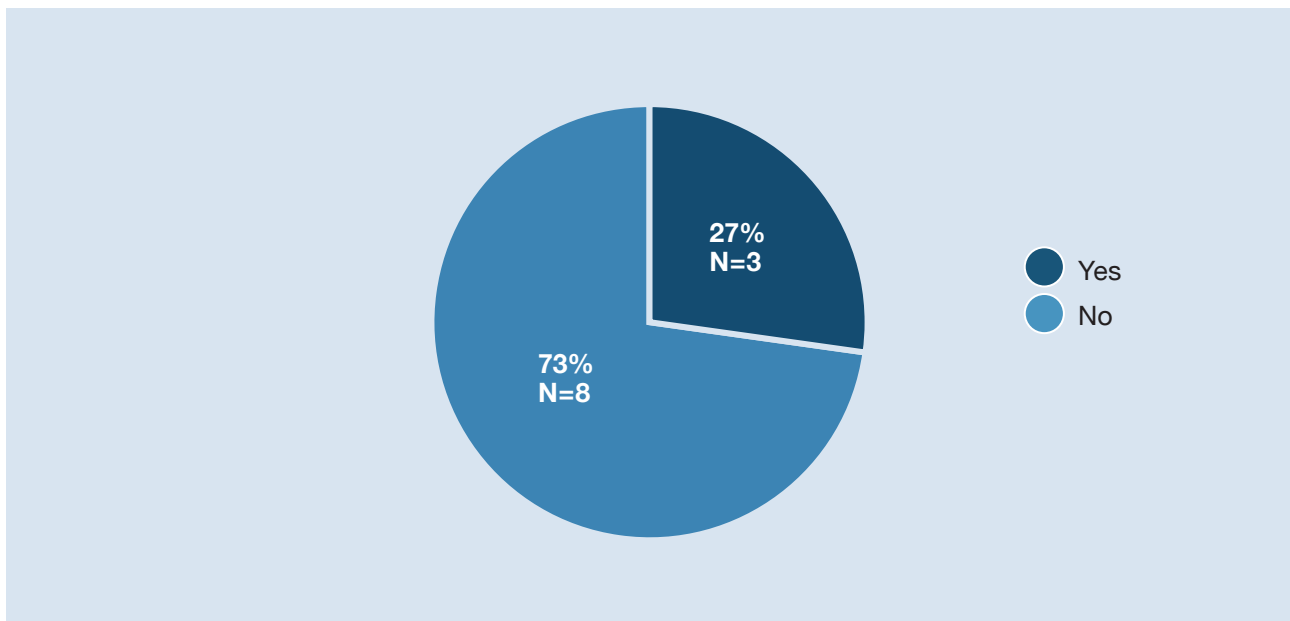
Is there any legal protection for the cervical screening programme in relation to cancers arising post screening?

Three countries/regions have legal protection in place for interval cancers arising in the screened population.

Two countries provided further information on their legal protection as follows:

- *There is indemnity from the Country risk pool. If there is a successful legal claim then the risk pool proforma is completed and returned to recoup costs*
- *Patients who might have been adversely affected still have to engage via medical legal processes*

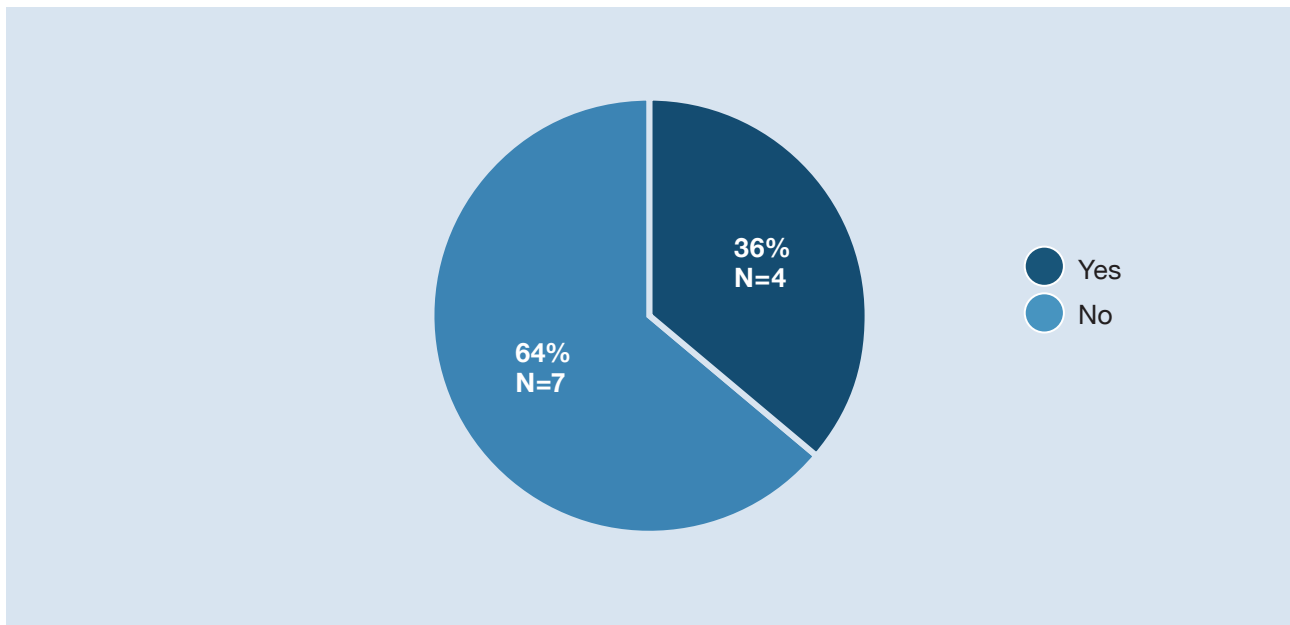
Figure 11. Is there any legal protection for the cervical screening programme in relation to cancers arising post screening?



In your country/programme is there any financial compensation for interval cancers?

Four countries/regions have financial compensation for interval cancers. Details from these countries regions include the following:

- *There has to be proof of screening incident rather than a limitation of screening*
- *The country's patient insurance system covers all patients treated by health care services. If a complaint is made, it is reviewed by the patient insurance and decided upon. The "Patient Ombud" is a sort of "ombudsman" system allowing for complaints as to treatment received and decisions on made by a.o. the patient insurance. The law from 2010 is called: Act on Complaints and Compensation in the Health Service*

Figure 12. In your/country programme is there any financial compensation for interval cancers?

Do you capture interval cancer rates for an internal report?

Six countries/regions capture interval cancer rates for internal reporting purposes.

Do you publish your interval cancer rates?

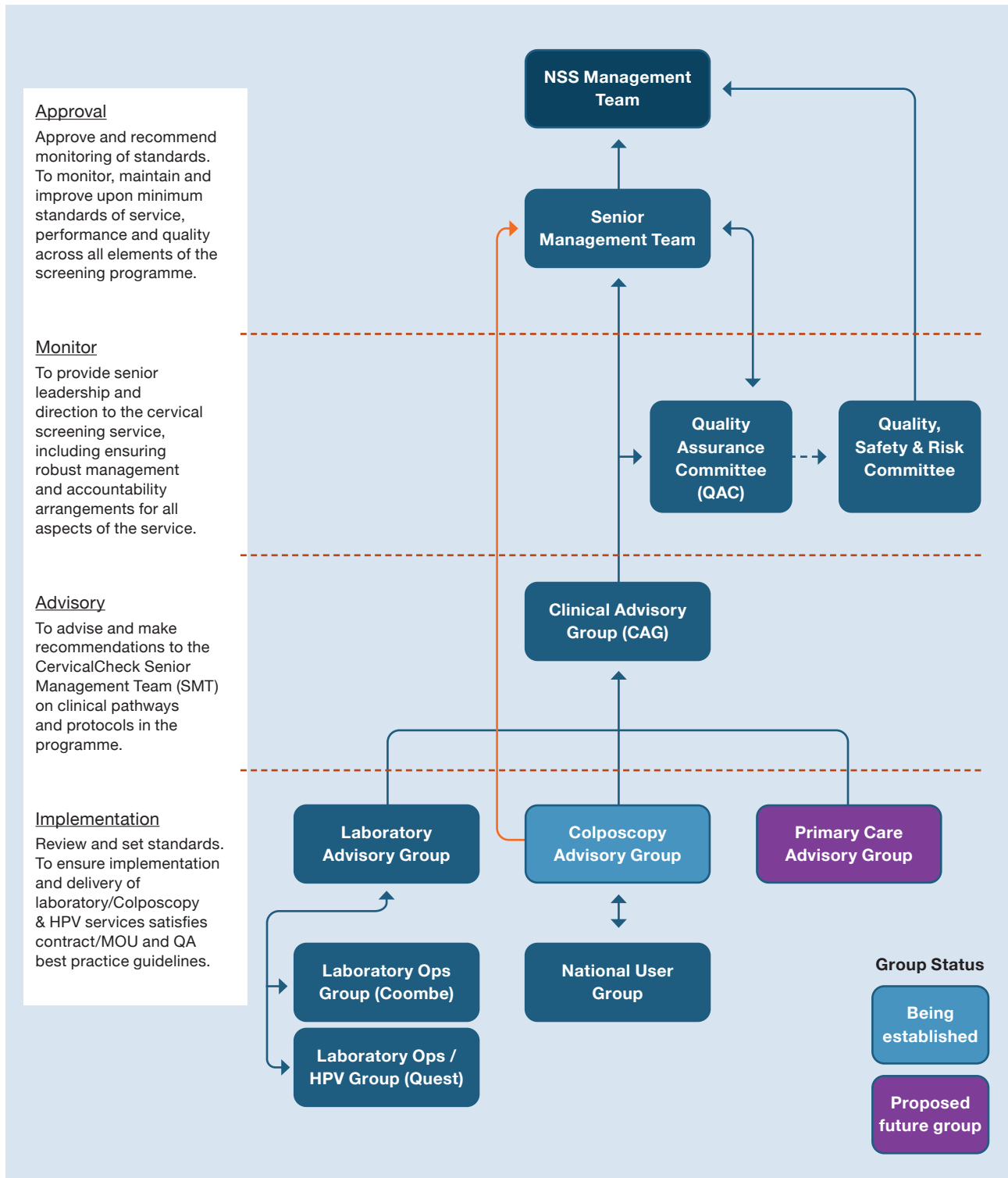
Five of the countries/regions publish their interval cancer rates. Some comments received in relation to this are as follows:

- *We used to publish annual reports (but have always been reluctant)*
- *Feedback is communicated to clinicians involved in screening on annual educational days of the national cervical screening programme.*
- *Results of the audit are used by the national screening programme for the targeted educational purposes - the aim of the audit is to identify a systematic problem that can be eliminated/minimized in the future with targeted actions.*
- *The quality database on cervical screening is issued annually evaluating eight key performance indicators per laboratory, per region and for the country as a whole, a.o. number of cervical cancer cases. Interval cancers are not reported specifically.*

Table 1. Summary of survey results by country/region

Country/Region	1	2	3	4	5	6	7	8	9	10	11
Audit of interval cancers	*	*	*	*	*	*	*	*	*	*	*
Use control samples	*					*	*		*		
Reviewers blinded to cancer status	*						*		*		
Different audit procedure for individuals						*	*		*		
Inform patients that an audit is taking place			*		*						*
Choice to participate								*			
Consent captured to take part in a clinical audit							*				
Routine consent procedure for screening covers the IC audit process		*		*	*			*	*	*	*
Results of audit communicated to the affected patients			*		*	*					*
Ask women if they want to know the outcome of the audit			*		*						*
Open disclosure policy for medical incidents	*	*	*			*		*	*		
Mandatory open disclosure policy		*	*			*		*			
Open disclosure policy extends to the results of audit of interval cancers			*			*		*			
Legal protection for cancers arising post screening	*		*								*
Financial compensation for interval cancers		*				*		*			*
Interval cancer rates reported internally			*	*	*	*	*		*		
Publish interval cancer rates		*	*			*	*		*		

Appendix 3: CervicalCheck Governance Structure



Appendix 4:

Summary of Literature Review

Summary of studies identified that have completed a retrospective review of interval cancers as part of a cervical screening programme

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
1	Cervical cancer screening in Europe: Quality assurance and organisation of programmes	Elfstrom M.K., et al	2015	Europe-wide survey	A comprehensive questionnaire was developed through systematic review of literature and existing guidelines. The survey was sent to programme organisers, Ministries of Health and experts in 34 European Union (EU) and European Free Trade Agreement (EFTA) countries. Detailed aspects of programme organisation, quality assurance, monitoring, evaluation and corresponding line-item costs were recorded. Documentation of programme guidelines, protocols and publications was requested.	Response: 29/34 Results showed: variation existed for QA, monitoring and evaluation, making it difficult to compare the cost-effectiveness of organisation and QA strategies. Most countries found it hard to estimate the costs associated with launching and operating the organised programme.	The results of this survey can be used as a basis for further development of standardised guidelines on organisation and QA of cervical cancer screening programmes in Europe.
2	European Guidelines for Quality Assurance in Cervical Cancer Screening. Second Edition—Summary Document	Arbyn, M. et al	2010	Europe: Europe Against Cancer Programme.	2nd Edition Guideline prepared by a multidisciplinary team of experts appointed by the European Commission from the former European Cervical Cancer Screening Network (ECCSN) established under the Europe Against Cancer Programme.	Key: programme design must permit evaluation. Guidance outlines on screening policy, screening organisation, monitoring and evaluation, new screening technologies, cytological methods, HPV detection, guidelines for cytology laboratories, guidelines for histopathology, complementary strategies of cervical cancer Prevention	Population-based programme policies which minimise adverse effects and maximise benefits of screening

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
3	The legal framework for European cervical cancer screening programmes	Majek O. et al	2018	28 countries of the EU, with the United Kingdom included as 4 countries; 4 EFTA member countries: Iceland, Liechtenstein, Norway, and Switzerland)	An electronic questionnaire including questions on governance, decision-making structures and legal framework was developed.	The legal framework makes it possible to personally invite individuals for screening in 29 countries (88%)	Comprehensive legal framework is needed to ensure high quality cancer screening - Majority of EU/ EFTA countries have implemented population-based cervical screening - Only half of those countries have successfully performed record linkage studies - Countries must improve their legal basis to allow for necessary programme monitoring
4	Mortality audit of the Finnish cervical cancer screening program	Lönnberg, S. et al	2012	Finland	Audit of screening histories of cervical cancer deaths and conducted a case-control evaluation of the effectiveness of organized screening in different ages with mortality as outcome.	Squamous cell carcinoma constituted 59% of the cases, adenocarcinomas 29%, and the remaining 12% were other specified and unspecified cervical malignancies. Most deaths (54%) were due to cancers diagnosed more than 5 years after last screening invitation, 24% were diagnosed among non-attenders and only 14% of deaths occurred among women who had attended invitational screening.	The risk reduction associated with attending a single program screen at an age below 40 was non-significant while clear risk reductions were observed after screening at the age of 40–54 and 55–69.
5	Guidance document: Adverse events reporting and management with particular reference to delayed diagnosis of cancer	Hynes, M & Keane, T	2009	Ireland	To describe the reporting and management of adverse events in Cancer Centre with particular reference to delayed diagnosis of cancer		

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
6	A review of cervical cancer occurrences in New Zealand 2008–2012	Hider, P. et al	2018	New Zealand	Review of the screening histories of those diagnosed with cervical cancer: women aged 25–69 years with confirmed cervical cancer underwent a review of their screening history. Cervical cancer incidence rates were calculated using Statistics New Zealand mid-year population estimates.	Only 13% had an adequate screening history over the 84 months prior to diagnosis. Women with cancer under age 45 years were more likely to have been screened than older women.	On-going review of cervical cancer occurrences is an important aspect of quality assurance for the national cervical cancer prevention strategy.
7	Policies and Standards: National Cervical Screening Programme - Providing a Colposcopy Service	Ministry of Health, New Zealand	2013	New Zealand	Their purpose is to support all those involved in the NCSP to achieve the programme's aims and objectives by ensuring a high standard and national consistency of service at each step of the screening pathway.		
8	Screening-Preventable Cervical Cancer Risks: Evidence From a Nationwide Audit in Sweden	Andrae, B. et al	2008	Sweden	all invasive cervical cancer cases that were diagnosed in Sweden from January 1, 1999, through December 31, 2001 were identified and verified the diagnoses by histopathology re-review and matched each case subject to five.	Women who were not screened had a higher risk of cervical cancer (including advanced cancers) than women who had been screened.	Nonadherence to screening intervals was the major reason for cervical cancer morbidity. The screening program was equally effective for women of all ages and was also effective against nonsquamous cancers.
9	Cervical cancer case-control audit: Results from routine evaluation of a nationwide cervical screening program	Wang, J. et al	2019	Sweden	a refined case-control cervical cancer audit framework to investigate effectiveness of cervical screening, with measures of three screening failures: irregular-participation, cervical cancer developed after cytological abnormalities and after normal screening results. The register-based study included 4,254 cervical cancer cases diagnosed in Sweden during 2002–2011, and 30 population-based controls per case.	Women unscreened in past 2 screening rounds showed 4 times increased risk of cervical cancer compared to women screened in time and women unscreened in the previous round but screened in the most recent round also showed a statistically significantly higher risk. Women with abnormal results in previous two rounds had higher risk of cervical cancer compared to women screened with normal results, while having normal results in the subsequent round after the abnormality also yielded an increased risk.	Findings emphasize the importance of routine participation in cervical screening and suggest that management of abnormalities, as well as sensitivity of the test, warrants improvement especially for preventing cervical adenocarcinoma.

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
10	Addendum: Audit of invasive cervical cancers: colposcopy review 2013-14	NHS Cervical Screening Programme, Tidy, J.	2012	NHS Cancer Screening Programmes	Guidance on how to include data on colposcopy into the audit of invasive cervical cancers.		For all cases, the following four questions must be answered: 1. Was the colposcopic management of the woman appropriate? 2. If not, could this have resulted in a failure to prevent the development of cervical cancer, or led to a delay in the diagnosis of cervical cancer? 3. Was there an inappropriate delay in treatment of high-grade CIN or high-grade CGIN? 4. If there was, was the colposcopy clinic responsible for this delay?
11	Addendum 3: Coding guide for the audit of invasive cancers	NHS Cervical Screening Programme, Castanon, A.	2013	NHS Cancer Screening Programmes	Guidance on coding for the audit of invasive cervical cancers, deciphering which data items are required for the audit and what are the different result codes?		
12	Disclosure of audit results in cancer screening: Advice on best practice	Patnick, J.	2006	NHS Cancer Screening Programmes	Guidance on advise on the best practice for passing on information about the results of audit of an individual case to the individual concerned and how to deal with any related medico-legal aspects. Developed by a multidisciplinary group	Considers psychological aspects, what information patients want, HCP stress mitigation, informing patients about audit and communication of results. Medico-legal aspects include consent, access to records, complaints and causation.	Advice is provided in how to consider these facets.
13	Protocol changes for 2012-13audit of invasive cervical cancers:	NHS Cervical Screening Programme	2012	NHS Cancer Screening Programmes	This document outlines changes to the audit protocol described in NHS Cervical Screening Programme. The aim is to improve the audit by linking it more closely to training, by streamlining and standardising procedures to ensure consistency across all Quality Assurance Reference Centres, and by providing clearer and tighter guidance to remove ambiguities.		The recommendations represent minimum standards, and attempts to exceed the guidance where this is felt to be locally valuable are encouraged.

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
14	Audit of invasive cervical cancers NHSCSP	NHS Cervical Screening Programme	2006	NHS Cancer Screening Programmes	Developed by a multidisciplinary group. The aim of this publication is to define a national protocol for audit of cases of invasive cervical cancer in order that standardised data can be pooled and analysed meaningfully.		Outlines audit sequence from national to local level. Detail includes arrangements for audit, review processes (cytology/ colposcopy/ histology/ regional panels/reporting findings/ treatment audit/evaluation and epidemiology)
15	Standard Operating Policy & Procedure (SOPP): Quality Standards – Audit	Cervical Screening Wales (CSW)	2013	Wales	SOPP on cervical screening audit specific to Wales		Description of CSW responsibility, laboratory services, colposcopy review process, audit process, disclosure.
16	Policy for clinical audit of new cases of invasive cervical cancer and disclosure of results	NHS Derby Teaching Hospitals	2015	Derby, England	Local policy for clinical audit of new cases of invasive cervical cancer and disclosure of results		Management of the Audit of New Cases of Invasive Cervical Cancer, Reporting Audit Findings, Audit & Disclosure Pathway, Disclosure of results, Monitoring compliance and effectiveness
17	Presentation: Cervical Screening Wales Audit of Cervical Cancer Process	Cervical Screening Wales (CSW), NHS Wales, Public Health Wales	2018	Wales	Presentation on CSW Audit Process: Cancers diagnosed on or after 1st April 2009, based on NHSCSP Publication 28 'Audit of Invasive Cervical Cancer' inclusive of women resident in Wales at time of diagnosis are reviewed by clinical lead on; type of cervical cancer, stage, treatment, and screen detected.	Notes: Cytology may be used for education if felt to be of benefit. Colposcopy, CL writes to lead colposcopist if there are any lessons to be learned Admin may be recorded as incident	Describes entire process including disclosure.
18	Disclosing the results of the invasive cervical cancer review to patients: a survey of lead colposcopists across England	Sherman, S.M. et al	2015	England	An online survey was sent to lead colposcopists (n=178) across England asking whether they offered the review to patients, if they did how they did so and what their experience was and if they did not, why not.	122 leads responded. 53% of respondents offered review meetings. Patients were predominantly invited to the review meeting face to face and clinicians' experiences were mixed: positive and negative. Those not offering a meeting (47%; n=57) there were a variety of reasons: 25% - lack of awareness of the guidelines, 19% - time constraints, 12% a fear of causing additional distress and 2% a fear of litigation.	Not all clinicians offer review meetings to patients and those who do offer them do not always offer them to all women. Research to be conducted on patient needs. Need to engage clinicians more.

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
19	Guidance for the Disclosure of Audit Results in Cancer Screening	West Midlands Cancer Intelligence Unit	2007	West Midlands, England	Regional guidance adapted from the NHS Cervical Screening Programme 'Disclosure of audit results in cancer screening (2006)' as well as existing local policies and good practice.		Defines a screening history review, purpose of audit, disclosure and patient leaflet included.
20	Regulation 20: Duty of candour	Care Quality Commission	2015	NHS England	The introduction of Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust 1, which recommended that a statutory duty of candour be introduced for health and care providers.	Actions to meet the requirements of Regulation 20 outlined once awareness of a notifiable safety incident.	Section 8 of Reg 20. "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in— (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or (b) severe harm, moderate harm or prolonged psychological harm to the service user.
21	Editorial: Disclosure of cervical cancer audits: how to be honest without making matters worse	Herbert, A.	2013	England	An editorial reviewing guidance and practices – a discussion of an NHS cervical screening programme and European guidelines. Personal views considered.	Discussion on poor compliance combined with cytological under-call, interval cancers in young women, discrepancies in review diagnoses of equivocal cytological changes, cancers arising after treatment of high-grade CIN, accuracy of HPV tests.	Formal reports to be available and meetings with the patient to take place after treatment is completed, ¹ a preliminary report at the time of the MDT meeting enables clinicians to be aware of potential problems that patients or their relatives may ask about. This way the negative emotions can more easily be replaced by the 'trust and reassurance' to be gained by full disclosure of the events that led to the development of cancer.

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
22	Routine Audit of Large-Scale Cervical Cancer Screening Programs	Cuzick, J.	2008	England	An editorial reviewing guidance and practices – a discussion of an article by Andrae et al.	Discusses three broad groups of screening failures can be identified: 1) women who were not screened within the recommended interval; 2) women who were screened and found to have an abnormality, but who subsequently developed cancer; 3) women who were adequately screened within the recommended interval with apparently normal results, but who subsequently developed cancer.	This audit process allows evaluation of routine service screening, as opposed to extrapolation from clinical trials, and should be widely emulated for all types of mass screening programs and not only restricted to cervical screening.
23	Guidance on applying Duty of Candour and disclosing audit results	NHS Screening Programmes, Public Health England	2016	England	Guidance on the Duty of Candour and its application across the 11 NHS screening programmes	Notes the importance of screening for improvement of population health whilst acknowledging the limitations of screening: << Screening tests: • cannot offer 100% sensitivity (ability of the test to correctly identify all true positives – those with the condition or disease) • cannot offer 100% specificity (ability of the test to correctly identify all true negatives – those without the condition or disease). <<Both false positive and false negative results can result in harm to an individual. However, these are not unexpected findings and are a feature of all screening programmes. Screening programmes should operate within agreed parameters so they offer more benefit than harm to the screened population, at a reasonable cost to the NHS.	<<There are circumstances when a person who has been screened may experience severe or moderate harm. This may be because: • the condition screened for has not been detected and it is not treated early enough to improve the outcome for the patient – examples can include breast cancer, fetal anomaly and abdominal aortic aneurysm • the person with or without the target condition is harmed by the procedure for detecting the condition – examples include loss of a fetus due to amniocentesis and death from bowel rupture following colonoscopy • they experience psychological harm from being told they are screen positive (or screen negative) and then finding out that their true result is different. These are recognised harms of a screening programme and are therefore not 'unexpected' if the programme is operating within agreed standards.

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
						<p>Because of the nature of screening programmes, sometimes it can be hard for screening services to know how to distinguish between a false negative/false positive that has occurred because of the limitations of screening and a false negative/false positive that has occurred because something has gone wrong.</p>	<p>Therefore, when these events occur they should not be automatically treated as notifiable safety incidents. >> Pg. 7</p> <p><<Where an error may have occurred in the screening test or diagnostic part of the screening pathway, the review should explicitly consider and document:</p> <ul style="list-style-type: none"> • was the process for undertaking the screen or diagnosis correctly carried out according to NHS screening guidance? • is the programme operating to national standards and the national specification? <p>If the answer to either of these questions is no, then the audit review should:</p> <ul style="list-style-type: none"> • document that there has been a failure in screening process (handle in accordance with 'Managing safety incidents in NHS screening programmes' (PHE 2015) iii and 'The serious incident framework' (NHS England 2015) iv • specifically consider whether the failure to follow process has (or could have in the reasonable opinion of a health care professional) contributed to the person being seriously or moderately harmed.>> Pg. 9

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
24	Implementing the national invasive cervical cancer audit: a local perspective	Moss E.L. et al	2010	England	Analysis of data from invasive cervical cancer reviews.	87 women were diagnosed with cervical cancer during the 3-year study period. The 'lapsed attendee' group accounted for the greatest number of cases (30%), followed by screen detected (26%), interval cancers (13%), never attended (12%), lost to follow-up (10%) and never invited (9%). Women who had never attended for cytology presented with higher stage disease, stage-II or above, compared with the screen-detected cases: 60% were stage II or above.	The categorisation of cervical cancer cases has the potential of yielding invaluable information for improving programme effectiveness. Patient compliance is the greatest challenge to the screening programme, and the need for regular screening and adherence to follow-up regimens needs to be reinforced in order to maximise the efficacy of the national screening programme.
25	NHSCSP Audit of Invasive Cervical Cancer: National Report 2009-2013	Sasieni, P. & Castanon, A.	2014	NHS England	Report focuses on 8,784 women who had a confirmed diagnosis of cervical cancer between April 2009 and March 2013. They are compared to 17,270 women without cervical cancer.	Almost half (47%) of all the cases diagnosed in women aged 25-49 are microinvasive cancers (stage 1A). 36% are stage 1B. However, in women aged 50 to 64, 49% of cancers are stage 2 or worse. Over 76% of stage 1A1 cancers were treated conservatively (by cone biopsy, loop excision or trachelectomy). In comparison, only 48% of stage 1A2 cases were treated conservatively.	Concordance between original result and review result was 59% for cytology and 90.2% for histological samples.

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
26	NHSCSP Audit of invasive cervical cancer National report 2007-2011 Cancer	Sasieni, P. & Castanon, A.	2012	NHS England	The NHS CSP audit comprises 8,566 women with confirmed diagnoses of cervical cancer (an estimated 90% of all cervical cancers in England), who are compared to 25,722 controls.	<p>There was an increase in the number of cervical cancers diagnosed in women under the age of 65 in 2008/09, due to the so-called 'Jade Goody effect' (this increase continued for several months after the reality star's death). Most of the excess cases were FIGO stage 1A.</p> <p>There was a shift towards earlier stage cancers in 2009-10. The numbers of advanced cancers (FIGO stage 2+) in the audit decreased by 10%, from 378 in 2007/08 to 344 in 2009/10.</p> <p>Data for the period September 2009-August 2010 showed a 22% reduction in cervical cancer incidence in women aged 65 and over, compared to data from September 2007-August 2008.</p>	Of all the negative tests that were reviewed, only 51% remained negative when investigated for a second time. 43% of the borderline tests remained borderline, and 41% of those showing low-grade dyskaryosis were confirmed as such.
27	NHS Cervical Screening Programme Colposcopy and Programme Management	NHSCSP, Luesley, D.	2016	NHS England	Review of guidance on management of women in the NHS Cervical Screening Programme	Findings of previous audits used to substantiate standards.	Since its introduction, the screening programme has helped half the number of cervical cancer cases, and is estimated to save approximately 4,500 lives per year in England. In 2014 to 2015 approximately 3.1 million women were screened in England.
28	Presentation: How invasive cervical cancer audit affects clinical practice	Herbert, A	Year not available	Guy's & St Thomas' Foundation NHS Trust, England	Presentation considers national guidance against European, comparing data between Guy's & St Thomas' and Southampton.	<ul style="list-style-type: none"> • 10% of women in England have no cytology test recorded on the central computer • Many of these (in London at least) have been previously screened outside the UK • Some are too young to have been offered screening within 3 years (<25) others too old (70+) <p>Looks at case histories.</p>	Considers aim of screening: 100% coverage. This therefore means that if every woman has been screened all cancers will be 'interval cancers'.

Ex. A-10


	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
29	Public health functions to be exercised by NHS England Service specification No.25 Cervical Screening	Cancer Screening, Early Diagnosis and Skin Cancer Prevention Team Department of Health	2013	NHS England	Guidance advising on the best practice for passing on information about the results of audit of an individual case to the individual concerned and how to deal with any related medico-legal aspects.	Functions of particular aspects of screening outlined	
30	Review of cytology and histopathology as part of the NHS Cervical Screening Programme audit of invasive cervical cancers	Castanon, A. et al	2011	England	Cervical cytology and histology slides taken within 10 years of diagnosis were identified and where possible reviewed after a nationally agreed protocol of 6113 women diagnosed with cervical cancer between 2007 and 10. Reviewers were not blinded to the original reading of each sample.	Of 13 745 cytology results from women developing cervical cancer, 55% were reviewed. The review result was identical for 55% of slides. Of 3759 originally normal slides, only 45% were normal on review: 11% were inadequate, 21% low grade (borderline or mild dyskaryosis) and 23% high grade (moderate dyskaryosis or worse).	In spite of the excellent quality of cytology in England, a high proportion of negative cytology taken up to three and a half years before diagnosis were considered to contain abnormal cells by reviewers informed of the subsequent cancer. Continuing these reviews, with a strong focus on education, will ensure a clear understanding of these slides and further reduce the risk of developing cervical cancer.
31	Review of invasive cervical cancers and uptake of disclosure of results: an audit of procedures and response	Prabakar, I. et al	2012	England	Following a review of 98 invasive cervical cancer diagnoses between 2003 and 2007, women were classified into two categories: a) (n=61) who developed invasive cancer despite adherence to the screening programme/ management or diagnostic decision was determined to have been a principal factor in the development of their disease, b) (n=36) a group who either had never undergone a cervical smear or had been established defaulters from the screening programme.	Sixty of the 61 women in Group A were sent an invitation to discuss the results of their case Review - 24 (40%) chose to attend. Thirty-six (37%) were classified as Group B, and it was deemed neither appropriate nor possible to invite the patients for a review consultation.	A policy of selective invitation for the disclosure of invasive review results is feasible. Less than one-half of patients diagnosed with cervical cancer appear to want to know how they developed cervical cancer despite previously participating in a screening programme.

Ex. A-10

	Title	Authors	Year	Screening setting	Study Design	Results / Main findings	Conclusion
32	The NHS cervical screening programme audit of invasive cervical cancers: who benefits?	Moss, E.L. et al	2011	England	A review of NHS cervical screening policies against existing evidence examining the rationale for auditing and disclosure. No clear methodology noted.	Audit: necessary for quality and learning. Disclosure: two findings are of particular relevance: first, women who had had adverse events disclosed to them were twice as likely to rank their care as good or excellent compared with those who had not had events disclosed to them; second, lower quality ratings were associated with events that still adversely affected the woman at the time of the survey.	Incorporating case review into the national audit with the publication of a triennial report, although time consuming, would help to maintain confidentiality because of the large number of cases and could enable lessons to be learnt, thereby demonstrating that the NHSCSP is doing everything possible to reduce the number of preventable cervical cancers. Closing note: a more fundamental question remains unanswered; is universal unsolicited disclosure beneficial or detrimental to the wellbeing of the women concerned?
33	Invasive cervical cancer audit: why cancers developed in a high-risk population with an organised screening programme	Herbert, A. et al	2010	England	Observational study of CIN2+ (CGIN, CIN3 and CIN2) and invasive cervical cancer diagnosed at Guy's and St Thomas' NHS Foundation Trust in 1999–01, 2002–04 and 2005–07. Audit of screening histories of women with invasive cancer analysed according to route to diagnosis, histological type and International Federation of Obstetrics and Gynecology (FIGO) stage.	133 invasive cancers, 53 CGIN, 1502 CIN3 and 1472 CIN2. Screen-detected cancers in asymptomatic women comprised 48.9% of cancers and were successively more likely to be in younger age groups ($P = 0.03$); all except one were stage IA or IB1. Screen-detected IA cancers were more likely ($P < 0.001$) to be in women screened within 0.5–5.0 years (80.5%) than screen detected fully invasive (58.3%) or symptomatic cancers (35.3%). Seventy-one (53.4%) women had been screened within 0.5–5.0 years; 11 had negative cytology within 0.5–3.5 years and two tests within 10 years. The other 60 had negative tests less frequently or had previous abnormal cytology, colposcopy or treatment. Potentially avoidable factors were often multiple, including false-negative cytology, high-grade cytology reported as low-grade and lapses in attendance either	While often potentially avoidable, cancers in previously screened women tended to be early stage, detected by cytology and rare when compared with high-grade CIN.

Appendix 5a

Letter to Expert Reference Group post RCOG



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Office of the Chief Clinical Officer
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Oifig an Príohóigeach
Cliniciúil Eatromhach Ospidéal
Dr. Steeven, Baile Átha Cliath 8, D08 W2A8

By Email Only

11th December 2019
Prof. Susan O'Reilly

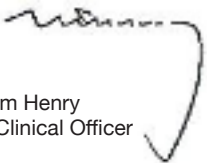
RE: Interval Cancer Audit & Review - BreastCheck Expert Reference Group

Dear Susan,

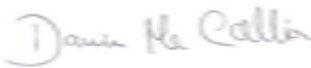
The aggregate report of the Independent Clinical Expert Panel Review of Cervical Check, completed by the Royal College of Obstetrics & Gynaecology was published on the 3rd December 2019. The report makes ten recommendations overall and recommendation four; five and six specifically refer to clinical audit of cancers in the screening programme.

The Minister is requesting that the Expert Reference Group for Bowel and Cervical Screening would consider these recommendations in relation to international best practice and the functioning of the screening programme.

I wish to acknowledge the significant work, which has been completed to date by the Expert Reference Group and welcome your feedback regarding these recommendation before the end of January 2020.



Dr Colm Henry
Chief Clinical Officer



Damien McCallion
HSE National Director
Emergency Management &
Director General CAWT

Appendix 5b

Response from Expert Reference Group post RCOG

The Royal College of Obstetricians and Gynaecologists (UK) Independent Expert Panel published their review on Cervical Screening in Cases of Cervical Cancer in Ireland between 2008-2018 on December 3rd, 2019. Their report made 10 recommendations.

The Minister of Health requested that the Expert Reference Group for Bowel and Cervical Screening would consider recommendations 4, 5 and 6 in relation to international best practice and the functioning of the screening programme. The Expert Reference Group thought it best to respond to all 10 of these recommendations in the RCOG report.

Recommendation 1

The policy of reviewing cytology slides in the knowledge that women have subsequently developed cancer should be viewed as a reliable and effective method of audit. This Review did not find evidence of bias and provides reassurance about using this methodology in the future.

Expert Reference Group response:

The Expert Reference Group agrees with the statement that “the policy of reviewing cytology slides in the knowledge that women have subsequently developed cancer should be viewed as a reliable and effective method of audit”. Additionally, we believe that retrospective bias in reviewing cytology slides of patients diagnosed with cancer will be minimised by blinding the review process. This means mixing cytology slides of cancer patients with a proportion of cytology slides from women who have not been diagnosed with cancer.

Recommendation 2

Large scale reviews in the future should require slides to be transported in a way that allows them to be tracked, with adequate packaging protocols, and with back-up imaging, thus not placing irreplaceable diagnostic material at risk. This can be recommended for future use.

Expert Reference Group response:

The CervicalCheck Programme will take into consideration the comments on packaging and transportation of slides, should there be the necessity to do so. To minimise transportation requirements, the intent is to arrange for slide reviews to be conducted within Ireland by external experts.

Recommendation 3

Efforts should continue to inform women of the limitations of cervical screening, while at the same time reinforcing the message that the Irish National Screening Programme is in line with internationally respectable programmes and is reducing cervical cancer incidence and deaths. HPV primary screening and HPV vaccination will ensure cervical cancer becomes a rare disease in Ireland.

Expert Reference Group response:

The Expert Reference Group concurs with the recommendation to continue to inform women of the limitations of screening and to reinforce the message that the Irish CervicalCheck Programme is performing in line with internationally respected screening programmes.

We note that both web based information and patient consent forms have been continuously improved to reflect the benefits and limitations of screening and will be further revised to ensure the proposed approach to audit and access to individual reviews for women diagnosed with cancer is added subsequent to implementation of the recommendations in our report.

Ireland's relatively young national screening programme (commenced in 2008) is demonstrating the expected improvements in incidence and mortality. The full impact will be even more evident over time. The planned implementation of primary HPV screening in 2020 and HPV vaccination will further help reduce incidence and mortality.

Recommendation 4

A policy of prior cytology slide review following every diagnosis of cancer is an important audit exercise and should be an integral part of the programme. This should be conducted within a culture of candour with full disclosure of audit findings.

Expert Reference Group response:

The policy of cytology review following every diagnosis of cancer is regarded as an important audit exercise by the Expert Reference Group. This will be implemented subsequent to the start of primary HPV screening nationally. Of note, slides will be anonymised and blinded to the external reviewers. This educational review will be part of the quality assurance programme and will also form the basis of seminars and reports to facilitate training of professional staff.

The Expert Reference Group has also recommended a new process of patient-requested reviews for those diagnosed with invasive cervical cancer. If so, they will sign consent for this review to be undertaken. The cytology review will be blinded but does not need to be anonymised.

The provision of individually requested reviews will include a candid discussion of the findings with each patient.

Recommendation 5

Given the colposcopy findings, it is recommended that colposcopic management is included in the audit protocol. Women should be offered the findings of this audit by the colposcopy consultant with adequate time provided. This should be accorded the status of a 'breaking bad news' interview.

Expert Reference Group response:

The Expert Reference Group agrees that colposcopy management should be included. This will be addressed as part of the patient-requested individual reviews. The colposcopy consultant would typically be the professional discussing the review with the patient. Review of colposcopy is appropriate for patients diagnosed with cancer more than 6 months after attendance.

Recommendation 6

These audits should be published in an aggregate form periodically e.g. every five years in order to provide up to date information. Although it is expected that the conversion to primary HPV testing and the protection afforded by vaccination will reduce the number of such cases, it will remain important to understand whether or not opportunities to prevent cancer were missed.

Expert Reference Group response:

The Expert Reference Group agrees with the RCOG and recommends that the results of audits are published regularly. RCOG suggests every 5 years, but optimistically, reports could be published more often, once both programmatic cytology reviews and individually requested patient reviews are operating effectively. We recognise the importance of staff education and training, thus seminars and teaching sessions several times a year are a more intensive and timely means to enhance training.

Recommendation 7

There should be an emphasis on adhering to the CervicalCheck colposcopy practice guidelines that are in place. There needs to be greater awareness of mismatches between cytology, colposcopy appearance and biopsy results, with tighter adherence to multidisciplinary meetings for such cases. There needs to be greater awareness of the positive predictive value of the different smear grades, with for example, the appropriate weight of a high grade result being used to determine management. We found a number of cases where the colposcopy management was insufficiently pro-active.

Expert Reference Group response:

The Expert Reference Group agrees with adherence to the CervicalCheck colposcopy practice guidelines. It is recognised that the colposcopist must have a high level of awareness of "difficult to diagnose" occult cancer in women with high grade smears. We note that the RCOG review commented on 27 cases out of 106 women, who developed cancers over the several years being reviewed, where they thought the colposcopic management was suboptimal. CervicalCheck gynaecologists and nurse colposcopists conducted 19,500 new colposcopies per annum, thus the number of cases noted by RCOG is very small and does not indicate serious problems with the Programme. Nevertheless, RCOG appropriately highlights the need to continually address colposcopic performance in order to provide the best outcomes for all patients.

Notably, the implementation of primary HPV screening in 2020 will increase demand for colposcopy and make it even more vital that resources and staffing are delivered and that scrutiny of performance is integral to the Programme and the host hospitals. CervicalCheck appointed, in December 2019, a consultant gynaecologist as clinical lead for colposcopy services who will be responsible for quality assurance and planning.

Multidisciplinary team meetings are an important element of good clinical practice and are to be supported. There are logistical challenges in arranging timing for international laboratories that will need to be overcome.

Recommendation 8

There should be tighter scheduling in colposcopy management. We identified cases where there were delays in initial referral, between visits, and in scheduling treatment. It is recognised that some delays are due to non-attendance, but cumulative delays appeared in some cases to lead to a missed opportunity to prevent cancer.

Expert Reference Group response:

The Expert Reference Group agrees with Recommendation 8. The colposcopic management and scheduling will be further integrated with the primary screening operations and subject to appropriate monitoring.

The clinical lead for colposcopy will ensure that the work in recommendations 7 and 8 are coordinated and delivered between the screening programme and the hospitals.

Recommendation 9

We recommend the creation of a dedicated database of cancer screening histories in cases where cancer occurs. This could include HPV and cytology data as well as colposcopy and histology and dates of pre-cancer and cancer diagnosis.

Expert Reference Group response:

The Expert Reference Group agrees with this recommendation. There is work ongoing in CervicalCheck as part of primary HPV implementation to expand the existing screening KPIs and database to provide comprehensive information.

Recommendation 10

The collective experience that will have been gained through the process of disclosure to women of the findings of the RCOG Expert Panel, should be reviewed subsequently, and used to develop best practice guidance for disclosure protocol going forward.

Expert Reference Group response:

The Expert Reference Group agrees with this recommendation. The National Women and Infants Programme (Clinical Leader Dr Peter McKenna) are coordinating follow up letters to all women in the RCOG review who chose to have a meeting with doctors to discuss their findings. This feedback will be a key element in developing best practice re disclosure meetings.

Ex. A-10



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An tSeirbhís Náisiúnta Scagthástála
National Screening Service

 **CervicalCheck**
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THE NATIONAL CERVICAL SCREENING PROGRAMME